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Application No.	PCT/IE00/00045
Date of Filing	20 April 2000
Applicant	SALVIAC LIMITED, an Irish company of 39-40 Upper Mount Street, Dublin 2, Ireland.

Dated this 24 day of April 2001.

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PCT/IE 00/00045

PCT

REQUEST

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International Application No. PCT/IE 00/00045

International Filing Date 20 APR 2000

Name of receiving Office and "PCT International Application"

Applicant's or agent's file reference *(if desired) (12 characters maximum)* SALV17/P/WO

Box No. I TITLE OF INVENTION

An Embolic Protection System

Box No. II APPLICANT

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

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The person identified below is hereby/has been appointed to act on behalf of the applicant(s) before the competent International Authorities as: ☒ agent ☐ common representative

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☒ applicant and inventor

☐ inventor only *(If this check-box is marked, do not fill in below.)*

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Filing date of earlier application (day/month/year)	Number of earlier application	Where earlier application is: national application: country	regional application:* regional Office	international application: receiving Office
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This international application contains the following **number of sheets**:

request	: 4
description (excluding sequence listing part)	: 17
claims	: 5
abstract	: 1
drawings	: 13
sequence listing part of description	:
Total number of sheets	: 40

This international application is **accompanied by** the item(s) marked below:

1. ☒ fee calculation sheet
2. ☐ separate signed power of attorney
3. ☒ copy of general power of attorney; reference number, if any: 39802, 39845, 40262, 40277
4. ☐ statement explaining lack of signature
5. ☐ priority document(s) identified in Box No. VI as item(s):
6. ☐ translation of international application into (language):
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Figure of the drawings which should accompany the abstract: Fig. 21

Language of filing of the international application: English

Box No. IX SIGNATURE OF APPLICANT OR AGENT

Next to each signature, indicate the name of the person signing and the capacity in which the person signs (if such capacity is not obvious from reading the request).

John O'Brien

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"AN EMBOLIC PROTECTION SYSTEM"

Introduction

This invention relates to an embolic protection system in particular for temporary deployment of an embolic filter in a vasculature.

In our WO-A-99/23976 we have described a vascular filter and a guidewire, the guidewire having a flexible tip at its distal end to assist in navigation of the filter through a potentially tortuous vasculature system. The filter is delivered to a desired location in the vasculature in a delivery catheter. The filter is deployed at the desired location and the delivery catheter is removed over the guidewire. A separate treatment device such as a dilation balloon or a stent of the self-expanding or balloon expandable type is then delivered by a delivery catheter over the guidewire and deployed at the treatment location. After treatment, the treatment device is withdrawn over the guidewire. The filter is retrieved by introducing a retrieval catheter over the guidewire and pulling the filter back into the retrieval catheter, and with it, any embolic material captured by the filter during the treatment procedure.

This system is extremely efficient in effectively capturing embolic material distally while facilitating treatment proximally of the filter.

Ideally a range of such devices are provided to suit different procedures and/or patient anatomies.

There is however an economic and clinical need to provide a single system of this type that can be used in a wide range of different applications.

Statements of Invention

According to the invention there is provided an embolic protection system comprising:-

a guidewire for advancing through a vasculature, the guidewire having a distal end and a proximal end;

an embolic protection filter having a distal end, a proximal end, a retracted configuration and an expanded deployed configuration, the filter being movable along the guidewire;

a delivery catheter advanceable over the guidewire for delivery of the embolic protection filter; the delivery catheter having a proximal end and a distal end;

deployment means for deploying the filter from the distal end of the delivery catheter into the expanded deployed configuration;

a retrieval catheter advancable over the guidewire for retrieval of the filter, the retrieval catheter having a distal end and a proximal end; and

engagement means for engaging the filter with the guidewire.

In one embodiment of the invention the engagement means comprises an engagement portion on the guidewire and an engagement portion of the filter, the engagement portions being engagable to engage the filter with the guidewire.

In this case the engagement portion of the guidewire may comprise a guidewire abutment on the guidewire. The guidewire abutment is preferably located at the distal end of the guidewire.

In one embodiment the engagement portion of the filter comprises a filter abutment on the filter. In one case the filter abutment is a distal abutment on the filter. Alternatively, the filter abutment is a proximal abutment on the filter.

In another embodiment the engagement means comprises a releasable locking means between the filter and the guidewire.

In this case preferably the releasable locking means is a taper lock. The taper lock preferably comprises a locking ring on the guidewire, the ring having a tapered surface which is engagable with a corresponding tapered surface of the filter to lock the filter to the guidewire. The ring is preferably a split ring.

In a preferred embodiment the embolic protection system includes a tube advanceable over the guidewire, the locking ring being located between a distal end of the tube and the filter for retrieval of the filter.

In another embodiment of the invention the releasable locking means includes a tether engagable with the filter for retrieving the filter into the retrieval catheter.

Preferably the deployment means comprises means for moving the retracted filter relative to the distal end of the delivery catheter. Ideally, the deployment means comprises a tube which is advanceable over the guidewire for engagement with the proximal end of the filter, the tube being movable relative to the delivery catheter for deployment of the filter from the distal end of the delivery catheter.

In a preferred embodiment the embolic protection system includes loading means for loading the filter into the delivery catheter.

In one embodiment the loading means comprises a funnel having a narrowed portion receivable in the distal end of the delivery catheter and an enlarged portion for receiving portion of the filter in the expanded configuration, the filter being moved through the funnel for loading.

In a further embodiment of the invention the system includes engagement means for engaging the retrieval catheter with the filter. The filter and retrieval catheter engagement means may be a frictional engagement means. The engagement means typically comprises projections on the inner surface of the retrieval catheter adjacent the distal end thereof.

In one embodiment of the invention the delivery and/or retrieval catheter is a rapid exchange catheter having an elongate slot in a sidewall thereof.

In another aspect the invention provides a method for delivery, deployment and retrieval of a filter within a vasculature comprising the steps of:-

advancing a guidewire through a vasculature ;

delivering a filter over the guidewire to a desired location in the vasculature;

deploying the filter;

on completion of the interventional procedure advancing a filter retrieval catheter over the guidewire;

engaging the guidewire with the filter;

retrieving the filter into the retrieval catheter; and

withdrawing the guidewire and the filter from the vasculature.

Preferably the guidewire is engaged with the filter before retrieval of the deployed filter into the retrieval catheter.

In one case the guidewire is engaged with the filter intermediate deployment of the filter and retrieval of the deployed filter into the retrieval catheter

The guidewire may be engaged with the filter during deployment of the filter. Alternatively, the guidewire is withdrawn after withdrawal of the retrieval catheter and the filter from the vasculature. The guidewire may also be withdrawn during withdrawal of the retrieval catheter and the filter from the vasculature.

In a preferred embodiment after withdrawal of the filter from the vasculature, a treatment means is advanced over the guidewire.

The invention provides a clinician with the freedom to select from different guidewires prior to selection of an embolic filter.

Prior art assemblies suffer from the disadvantage that different guidewires cannot be used with a particular filter during an interventional procedure. A clinician is thus constrained to discard both the guidewire and the filter if the guidewire proves unsuitable, for example because it is too stiff, or some other mechanical property is undesirable.

An important advantage of the invention is that because the filter is not attached to the guidewire in a collapsed configuration for delivery, the guidewire which is first advanced through the vasculature has a lower profile. Therefore the guidewire alone can more easily navigate narrow and tortuous regions of the vasculature.

Another important advantage of the invention is that because the filter is not fixed to the guidewire, if the deployed filter is mis-sized with respect to the region of the treatment site it is free to be carried by blood flow to a distal narrowed section of the vasculature at which the filter effectively achieves apposition with the vessel wall. This ensures that all blood flow with entrained embolic material passes through the filter.

Brief Description of the Drawings

The invention will more clearly understood from the following description thereof given by way of example only with reference to the accompanying drawings, in which:-

Figs. 1(a) to 1(e) are schematic views of various guidewire elements of an embolic protection system of the invention;

Fig. 2(a) is an enlarged cross sectional view of the distal tip of the guidewire of Fig. 1(d);

Fig. 2(b) is an enlarged cross sectional view of the distal tip of the guidewire of Fig. 1(c);

Figs. 3 to 5 are schematic views of further elements of the embolic protection system;

Figs. 6 to 9 are schematic views of various filter elements of the embolic protection system;

Fig. 10 is a side partially cross sectional view of a guidewire, filter, delivery catheter and elongate member assembled for deployment;

Fig. 11 is a cross sectional view of a filter being loaded into the delivery catheter;

Figs. 12 to 14 are cross sectional views of other arrangements for loading the filter into the delivery catheter;

Fig. 15 is a side partially cross sectional view of the guidewire being advanced through a vasculature;

Fig. 16 is a view similar to Fig. 15 of the assembly of Fig. 10 advancing over the guidewire;

Fig. 17 is a view similar to Fig. 16 with the assembly adjacent a deployment site;

Fig. 18 is a view similar to Fig. 17 with the filter deployed;

Fig. 19 is a view similar to Fig. 18 with the inner elongate member and the delivery catheter retracted;

Fig. 20 is a view similar to Fig. 19 with a retrieval catheter advancing over the guidewire to the filter;

Fig. 21 is a view similar to Fig. 20 with the guidewire being retracted;

Fig. 22 is a view similar to Fig. 21 with the filter partially drawn into the retrieval catheter;

Fig. 23 is a view similar to Fig. 22 with the filter fully drawn into the retrieval catheter;

Fig. 24 is a view similar to Fig. 23 with the retrieval catheter, the guidewire and the retrieved filter being withdrawn from the vasculature;

Fig. 25 is a cross sectional view of a part of an assembly according to another embodiment of the invention prior to deployment of a filter in a vasculature;

Figs. 26 and 27 are views similar to Fig. 25 with the filter being deployed;

Fig. 28 is a view similar to Fig. 25 with a delivery catheter and an inner elongate member retracted;

Fig. 29 is a cross sectional view of a part of an assembly according to a further embodiment of the invention prior to deployment of a filter in a vasculature;

Figs. 30 and 31 are enlarged cross sectional views of part of the assembly of Fig. 29.

Fig. 32 is a cross sectional view of a rapid exchange version of the embolic protection system; and

Fig. 33 to 35 are cross sectional views of the system of Fig. 32, in use.

Detailed Description

Referring to Figs. 1 to 6 there is illustrated an embolic protection assembly according to the invention. The assembly comprises a plurality of different guidewires 1, an embolic filter 2, a delivery catheter 3, an inner elongate member 4 and a retrieval catheter 5.

A clinician selects a suitable guidewire 1 depending on personal preference, the geometry of the vasculature to be negotiated and/or the disease state. Each guidewire 1 has a soft, flexible distal tip 6, provided by a spring tip arrangement 21. Navigation of the guidewire 1 through a vasculature 8 is assisted by the soft tip 6.

If desired, the selected guidewire 1 may have an engagement means formed by an abutment surface 7 at the proximal end of the tip 6.

The outer diameter of the guidewires is typically in the range of from 10 to 21 thousands of an inch (2.54 mm to 5.334 mm).

The filter 2 comprises a membrane mounted over a collapsible support frame. The support frame is of superelastic material or a shape memory material such as Nitinol so that it can be collapsed inwardly for loading into the delivery catheter 3. On release from the delivery catheter 3 the filter 2 expands into an expanded deployed configuration. Such a filter is described in our co-pending PCT Application No. IE99/00033, filed May 7, 1999, the entire contents of which are incorporated herein by reference.

The filter membrane has large inlet openings 100 and small outlet openings 101 (Figs. 18 and 19). The inlet openings 100 allow blood and embolic material to enter the filter 2 and the outlet openings 101 allow through passage of blood but retain undesired embolic material within the filter 2.

The filter 2 is movable radially between a collapsed stored position against the guidewire 1, as illustrated in Fig. 10, and an expanded position, extending outwardly of the guidewire 1 for deployment in the vasculature 8.

A lumen 19 extends through the filter 2 and the filter 2 has an engagement grip 20 rigidly attached to the inner surface of the filter 2. In one embodiment of the invention the grip 20 is formed as a machined step in the filter 2 at the proximal end of the filter 2, as illustrated in Fig. 5.

In alternative embodiments of the invention the grip 20 is formed as a crimped region of the proximal end of the filter 2, as illustrated in Figs. 7 and 8.

In a further embodiment of the invention the grip 20 is formed as a welded insert at the distal end of the filter 2, as illustrated in Fig. 9.

The filter 2 is first loaded into the delivery catheter 3 in which it is retained in a collapsed state. In this configuration a distal end 15 of the inner elongate member 4 provides a proximal stop which locates the filter 2 at the distal end of the delivery catheter 3.

The filter 2 may be loaded into the delivery catheter 3 using a funnel 10 and a pulling device 13 as illustrated in Fig. 11. The pulling device 13 has a shoulder 17 which engages with the grip 20 to pull the filter 2 into the delivery catheter 3, thereby collapsing the filter 2.

It will be appreciated that the funnel 10 and the pulling device 13 may be used to load the filter 2 into the delivery catheter 3 when the grip 20 is rigidly attached to any point on the inner surface of the filter 2. Fig. 12 illustrates the loading of a filter 2 with the grip 20 attached to the inner surface at a distal region of the filter 2.

Alternatively, as illustrated in Fig. 13, the filter 2 may be loaded into the delivery catheter 3 using a funnel 10 and a pushing device 12. The pushing device 12 has a shoulder 17 which engages with the grip 20 to push the filter 2 into the delivery catheter 3, thereby collapsing the filter 2.

It will be appreciated that the funnel 10 and the pushing device 12 may be used to load the filter 2 into the delivery catheter 3 when the grip 20 is rigidly attached to any point on the inner surface of the filter 2. Fig. 14 illustrates the loading of a filter 2 with the grip 20 attached to the inner surface at a distal region of the filter 2.

In use, and referring in particular to Figs. 15 to 24, the guidewire 1 is first advanced through the vasculature 8 until the tip 6 is distal of a desired site such as a region of stenosis 16 in the vasculature 8 (Fig. 15). The delivery sub-assembly of the filter 2, the delivery catheter 3 and the inner elongate member 4 is advanced over the guidewire 1 to deliver the filter 2 to a desired site distally of the stenosis 16 (Figs. 16 and 17). When the filter has crossed the stenosis 16 the delivery catheter 3 is retracted relative to the inner elongate member 4 thereby releasing the filter 2 and allowing the filter 2 to expand to an expanded deployment configuration apposes the vasculature 8 (Fig. 18). The delivery catheter 3 and the inner elongate member 4 are then withdrawn over the guidewire 1 leaving the filter 2 and the guidewire 1 in position (Fig. 19).

Any suitable treatment device such as an angioplasty balloon may be subsequently advanced over the guidewire 1. A procedure such as an angioplasty is then carried out on the stenosis 16 to at least reduce and preferably remove it. On completion of the angioplasty procedure the treatment device is removed over the guidewire 1. If necessary, another treatment device such as an expandable stent may be advanced to the treatment site.

Embolic material released during the treatment procedure(s) is collected in the distal filter 2. To remove the filter 2, and with it the collected embolic material, a retrieval catheter 5 is advanced over the guidewire 1 until the retrieval catheter 5 is proximally adjacent the filter 2 (Fig. 20). The filter 2 is then drawn into the distal end of the retrieval catheter 5 by holding the catheter 5 in position and pulling the guidewire 1 proximally until the engagement abutment surface 7 engages the engagement grip 20 of the filter 2 (Fig. 21). Continued pull-back of the wire 1 pulls the filter 2 into the catheter 5 thereby collapsing the filter 2 as illustrated in Fig 22. When the filter 2 is retrieved to the collapsed configuration (Fig. 23) the retrieval catheter 5 and the guidewire 1 with the filter 2 in position is withdrawn from the vasculature 8 (Fig. 24).

The invention offers very considerable clinical advantages. The arrangement allows the clinician to select a suitable guidewire from a range of such guidewires. This provides enhanced flexibility by ensuring that filter performance can be optimised. The filter is not dedicated to a particular guidewire.

Because the filter is not attached to the guidewire, the guidewire which is first advanced through the vasculature can have a low profile. Consequently, the guidewire can easily navigate narrow and tortuous regions of the vasculature.

Thus, a clinician may readily select a particular type of guidewire which provides the appropriate flexibility and performance required for the particular vasculature procedure being performed. The system also facilitates the safe crossing of the lesion not only in a first lesion crossing procedure but also for any necessary follow-up procedures that may require re-crossing of the lesion.

Another important advantage is that because the filter is not attached to the guidewire, if the filter is mis-sized with respect to the region of the treatment site it is free to be carried by blood flow to a distal narrowed section of the vasculature at which the filter effectively achieves apposition with the vessel wall. This ensures that all blood flow with entrained embolic material passes through the filter. The grip 20 engages with a shoulder 7 of the guidewire 1 to prevent further distal movement of the filter.

Referring to Figs. 25 to 28 there is illustrated an assembly according to another embodiment of the invention, which is similar to the assembly of Figs. 1 to 24 and the same reference numerals are used to denote like elements in Figs. 25 to 28.

In this case the guidewire 1 has no abutment surface at the proximal end of the distal tip 6. The engagement means is provided by a tapered ring 18 which is slidably mounted around the guidewire 1 between the distal end 15 of the inner elongate member 4 and the proximal end 9 of the filter 2 to prevent migration of the deployed filter 2.

To deploy the filter 2 at a desired site in a vasculature 8, the delivery catheter 3 is retracted causing the filter 2 to initially move proximally due to the frictional force acting between the delivery catheter 3 and the filter 2. Proximal movement of the tapered ring 18 is prevented by the engagement of the distal end 15 of the inner elongate member 4 with the tapered ring 18. The proximal end 9 of the

filter 2 thus slides over the tapered ring 18, exerting an inward force on the tapered ring 18. The filter 2 is thus taper locked to the guidewire 1 by means of an interference fit between the filter 2 and the tapered ring 18, and an interference fit between the tapered ring 18 and the guidewire 1.

The filter 2 may be withdrawn by retracting the guidewire 1. To remove the filter 2, and with it the collected embolic material, a retrieval catheter 5 is advanced over the guidewire 1 until the retrieval catheter 5 is proximally adjacent the filter 2. The filter 2 is then drawn into the distal end of the retrieval catheter 5 by holding the catheter 5 in position and pulling the guidewire 1 proximally. This pulls the filter 2 proximally into the catheter 5 thereby collapsing the filter 2. When the filter 2 is retrieved to the collapsed configuration the retrieval catheter 5 and the guidewire 1 with the filter 2 in position are withdrawn from the vasculature 8.

Referring to Figs. 29 to 31 there is illustrated an assembly according to a further embodiment of the invention, which is similar to the assembly of Figs. 25 to 28 and the same reference numerals are used to denote like elements in Figs. 29 and 30. In this case a tether 30 with a hook 31 at its distal end extends between the delivery catheter 3 and the inner elongate member 4. The hook 31 arcs radially inwardly and is latched to the proximal end 9 of the filter 2 in the delivery configuration of Fig. 29. When the filter 2 is located at a desired site in a vasculature 8 the tether 30 is pulled back to draw the filter 2 proximally over the tapered ring 18. The filter 2 is thus taper locked to the guidewire 1 (Fig. 30). The delivery catheter 3 is then retracted to enable the filter 2 to expand to the deployed configuration. The hook 31 is released from the proximal end 9 of the filter 2 by advancing the inner elongate member 4 distally to urge the hook 31 radially outwardly (Fig. 31). The inner elongate member 4 and the unlatched tether 30 are then withdrawn from the vasculature 8, leaving the guidewire 1 with the filter 2 fixed to the guidewire 1 in the vasculature 8.

Referring to Figs. 32 to 35 there is illustrated a rapid exchange version of embolic protection system of the invention.

In this case the delivery catheter 3 has an elongate slit 50 through which a rapid exchange guidewire extends. The inner elongate member 4 also has a side entry hole 51 through which the guidewire 1 extends.

It will be appreciated that the guidewire may be left in place after the filter has been retrieved. In this case the guidewire may be used to deliver devices for carrying out further procedures.

Numerous vascular catheter functions are facilitated by the invention, such as:

(i) <u>Permits Dye Injections:</u>

After performing the therapeutic procedure (e.g., angioplasty or atherectomy), the filter can be retrieved if desired, in order to inject dye (over the remaining guidewire), such that minimal obstruction or interference occurs with the subsequent dye flow measurements. Alternatively, the wire can also be safely partially-retracted "behind" or "upstream" of the treated area, prior to performing the dye injection. Afterwards, the guidewire can be safely advanced in a distal direction to "re-cross" the treated area, without fear of causing significant disruptions to the lesion (such as causing an intimal tissue flap to tear loose and occlude the artery), in order to continue further therapeutic procedures. Similarly, the "barewire/filter" technique permits easier first crossing of vasculature of patients who had previously received vasculature stents.

(ii) Delivery of Lytic Agents:

Depending upon the physician's circumstances, lytic agents can be site-specifically delivered to the region of interest, either with the filter deployed, or with the distal filter retrieved, if desired.

(iii) Facilitates Stent Procedures:

Assuming appropriate design considerations have been incorporated, the retrieval sheath can also facilitate safe removal of the filter following a stenting procedure. For example, after deployment of an intravascular stent, the process of removing the filter favours certain sheath design considerations, such as a slight tapered, distal tip. Specifically, the distal tip of the sheath needs to permit easy crossing of the stent in a manner which will not catch up or "snag" at the proximal edge of the implanted stent, nor along any inwardly-projecting surface of the interior of the implanted stent, as the sheath is being introduced. More specifically, the distal region of the retrieval sheath is also preferably formed of a material which permits modest radial expansion at the distal tip in order to accommodate retrieval of the filter. It is expected that the distal tip would tend to close slightly following retrieval of the filter, thereby preventing inadvertent release of the filter during withdrawal of the filter/sheath system from patient.

(iv) Facilitates Guidewire Replacements:

Because this filter system accommodates barewire introduction, it is possible to replace a guidewire during a procedure, if desired. For example, during treatment of two or more, distally spaced-apart lesions, it may become necessary to replace the initial guidewire during the procedure with another guidewire offering improved steering or distal flexibility. The present invention might support such guidewire replacements as follows. First, the filter is retrieved into

the retrieval sheath (which has already crossed the first lesion area). Then the wire can be withdrawn (or alternatively, the wire and filter together can be withdrawn), while the sheath remains across the lesion. Subsequently, a replacement guidewire can be introduced through the sheath lumen to the area of interest.

A number of engagement means between the filter and the guidewire are described above which ensure that the filter is anchored or tethered while the retrieval sheath is advanced over the filter. It is also envisaged that an engagement means may be provided between the filter and the retrieval sheath after the filter is retrieved, to ensure that there is a positive engagement between the filter and the sheath. For example, frictional engagement means may be provided on one or both of the filter and sheath. For example, projections, rings, or the like may be provided on the inner surface of the retrieval sheath adjacent the distal end thereof to provide a frictional fit with the retrieved filter while allowing ease of release, if desired.

The invention is not limited to the embodiments hereinbefore described with reference to the accompanying drawings.

Claims

1. An embolic protection system comprising:-

a guidewire for advancing through a vasculature, the guidewire having a distal end and a proximal end;

an embolic protection filter having a distal end, a proximal end, a retracted configuration and an expanded deployed configuration, the filter being movable along the guidewire;

a delivery catheter advanceable over the guidewire for delivery of the embolic protection filter; the delivery catheter having a proximal end and a distal end;

deployment means for deploying the filter from the distal end of the delivery catheter into the expanded deployed configuration;

a retrieval catheter advancable over the guidewire for retrieval of the filter, the retrieval catheter having a distal end and a proximal end; and

engagement means for engaging the filter with the guidewire.

2. An embolic protection system as claimed in claim 1 wherein the engagement means comprises an engagement portion on the guidewire and an engagement portion of the filter, the engagement portions being engagable to engage the filter with the guidewire.

3. An embolic protection system as claimed in claim 2 wherein the engagement portion of the guidewire comprises a guidewire abutment on the guidewire.

4. An embolic portion system as claimed in claim 3 wherein the guidewire abutment is located at the distal end of the guidewire.

5. An embolic protection system as claimed in claims 2, 3 or 4 wherein the engagement portion of the filter comprises a filter abutment on the filter.

6. An embolic protection system as claimed in claim 5 wherein the filter abutment is a distal abutment on the filter.

7. An embolic protection system as claimed in claim 5 wherein the filter abutment is a proximal abutment on the filter.

8. An embolic protection system as claimed in any preceding claim wherein the engagement means comprises a releasable locking means between the filter and the guidewire.

9. An embolic protection system as claimed in claim 8 wherein the releasable locking means is a taper lock.

10. An embolic protection system as claimed in claim 9 wherein the taper lock comprises a locking ring on the guidewire, the ring having a tapered surface which is engagable with a corresponding tapered surface of the filter to lock the filter to the guidewire.

11. An embolic protection system as claimed in claim 10 wherein the ring is a split ring.

12. An embolic protection system as claimed in any of claims 10 or 11 including a tube advanceable over the guidewire, the locking ring being located between a distal end of the tube and the filter for retrieval of the filter.

13. An embolic protection system as claimed in any of claims 8 to 12 wherein the releasable locking means includes a tether engagable with the filter for retrieving the filter into the retrieval catheter.

14. An embolic protection system as claimed in any preceding claim wherein the deployment means comprises means for moving the retracted filter relative to the distal end of the delivery catheter.

15. An embolic protection system as claimed in claim 14 wherein the deployment means comprises a tube which is advanceable over the guidewire for engagement with the proximal end of the filter, the tube being movable relative to the delivery catheter for deployment of the filter from the distal end of the delivery catheter.

16. An embolic protection system as claimed in any preceding claim including loading means for loading the filter into the delivery catheter.

17. An embolic protection system as claimed in claim 16 wherein the loading means comprises a funnel having a narrowed portion receivable in the distal end of the delivery catheter and an enlarged portion for receiving portion of the filter in the expanded configuration, the filter being moved through the funnel for loading.

18. An embolic protection system as claimed in any preceding claim including engagement means for engaging the retrieval catheter with the filter.

19. An embolic protection system as claimed in claim 18 wherein the filter and retrieval catheter engagement means is a frictional engagement means.

20. An embolic protection system as claimed in claim 18 or 19 wherein the engagement means comprises projections on the inner surface of the retrieval catheter adjacent the distal end thereof.

21. An embolic protection system as claimed in any preceding claim wherein the delivery and/or retrieval catheter is a rapid exchange catheter having an elongate slot in a sidewall thereof.

22. A method for delivery, deployment and retrieval of a filter within a vasculature comprising the steps of:-

advancing a guidewire through a vasculature ;

delivering a filter over the guidewire to a desired location in the vasculature;

deploying the filter;

on completion of the interventional procedure advancing a filter retrieval catheter over the guidewire;

engaging the guidewire with the filter;

retrieving the filter into the retrieval catheter; and

withdrawing the guidewire and the filter from the vasculature.

23. A method as claimed in claim 22 wherein the guidewire is engaged with the filter before retrieval of the deployed filter into the retrieval catheter.

24. A method as claimed in claim 23 wherein the guidewire is engaged with the filter intermediate deployment of the filter and retrieval of the deployed filter into the retrieval catheter

25. A method as claimed in claim 22 wherein the guidewire is engaged with the filter during deployment of the filter.

26. A method as claimed in claim 22 wherein the guidewire is withdrawn after withdrawal of the retrieval catheter and the filter from the vasculature.

27. A method as claimed in claim 22 wherein the guidewire is withdrawn during withdrawal of the retrieval catheter and the filter from the vasculature.

28. A method as claimed in claim 22 wherein, after withdrawal of the filter from the vasculature, a treatment means is advanced over the guidewire.

Abstract

An embolic protection assembly comprises a plurality of different guidewires 1, an embolic filter 2, a delivery catheter 3, an inner elongate member 4 and a retrieval catheter 5. In use the guidewire 1 is first advanced through a vasculature 8. Then the delivery sub-assembly of the filter 2, the delivery catheter 3 and the inner elongate member 4 is advanced over the guidewire 1 to deliver the filter 2 to a desired site. The delivery catheter 3 is retracted to deploy the filter 2. The delivery catheter 3 and the inner elongate member 4 are then withdrawn. Any embolic material released during a procedure such as an angioplasty is collected in the filter 2. To remove the filter 2 a retrieval catheter 5 is advanced over the guidewire 1 and the filter 2 is drawn into the retrieval catheter 5 by pulling the guidewire 1 proximally until an abutment surface 7 of the guidewire 1 engages a grip 20 of the filter 2. The retrieval catheter 5 with the filter 2 in position are then withdrawn from the vasculature 8. The guidewire 1 may be withdrawn with the filter 2 or may be left in place for carrying out further procedures.

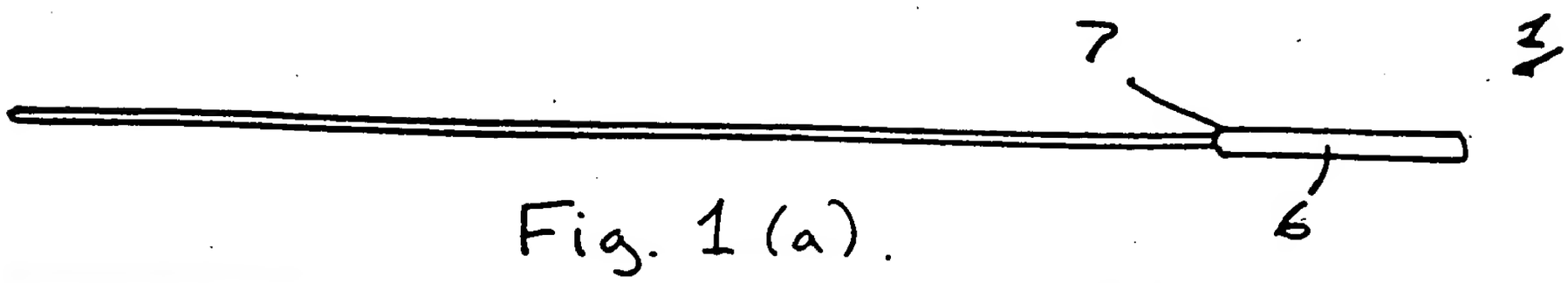

Fig. 1 (a).

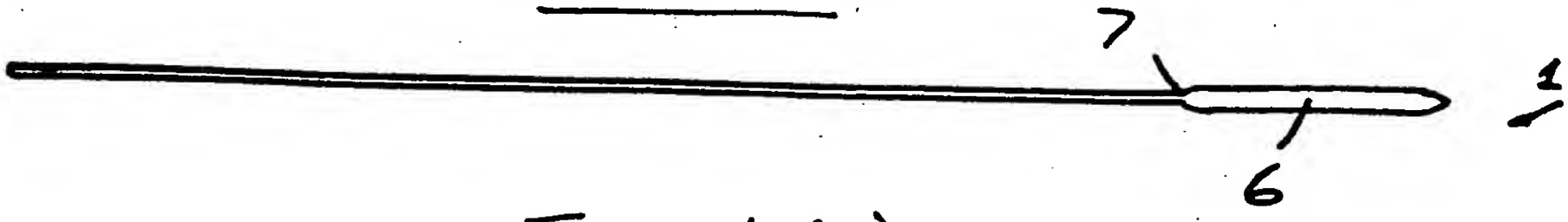

Fig. 1 (b).

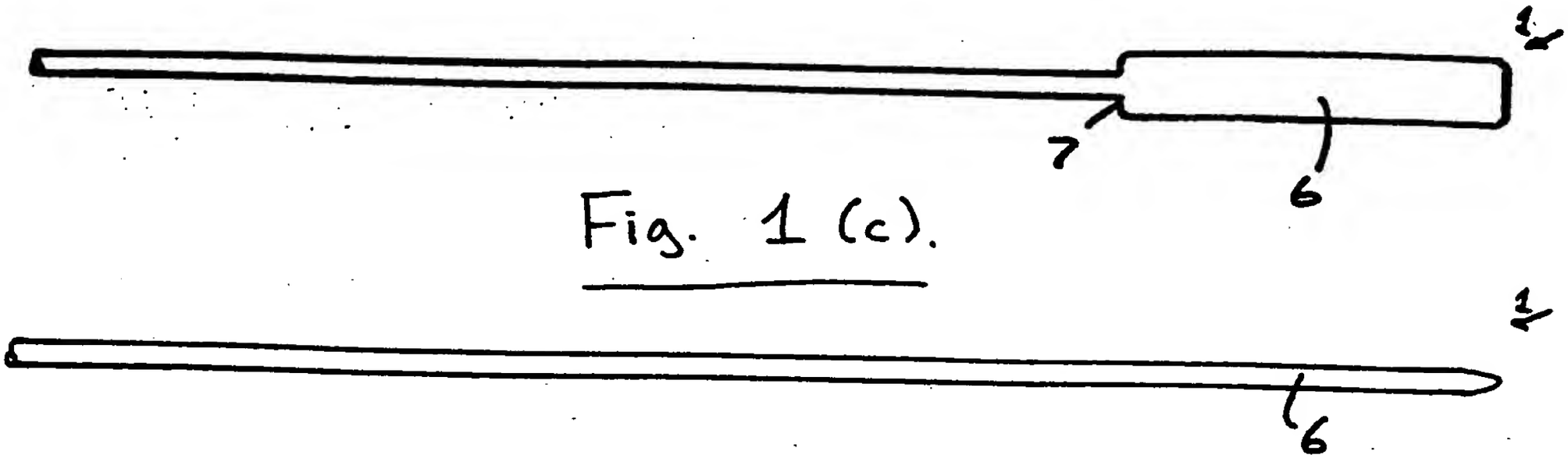

Fig. 1 (c).

Fig. 1 (d).

Fig. 1 (e).

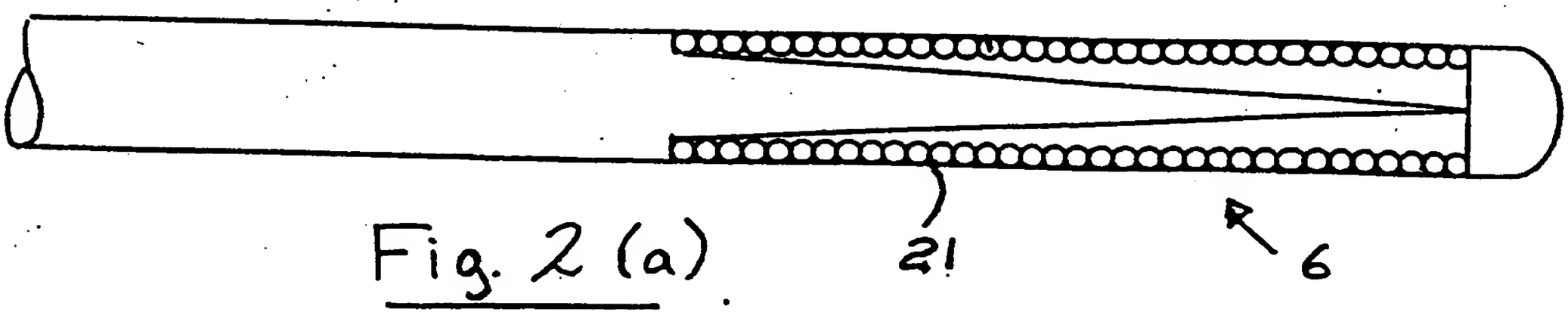

Fig. 2 (a)

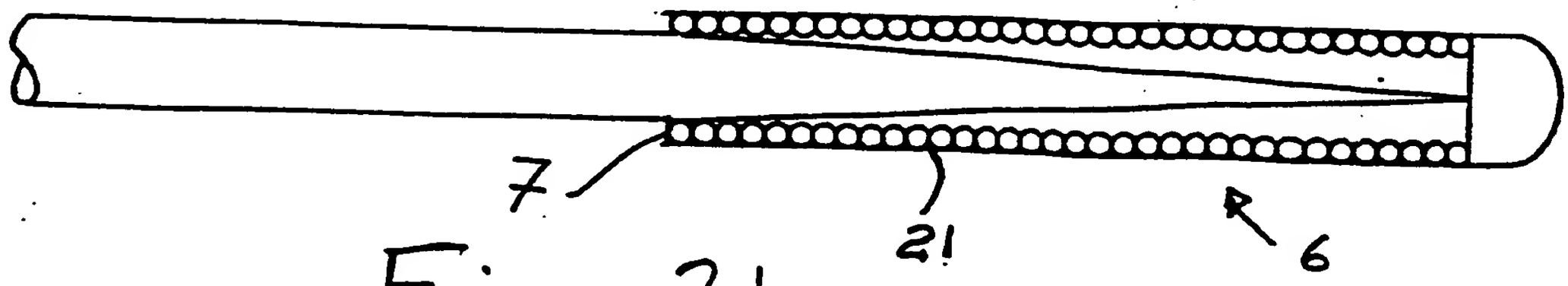

Fig. 2(b).

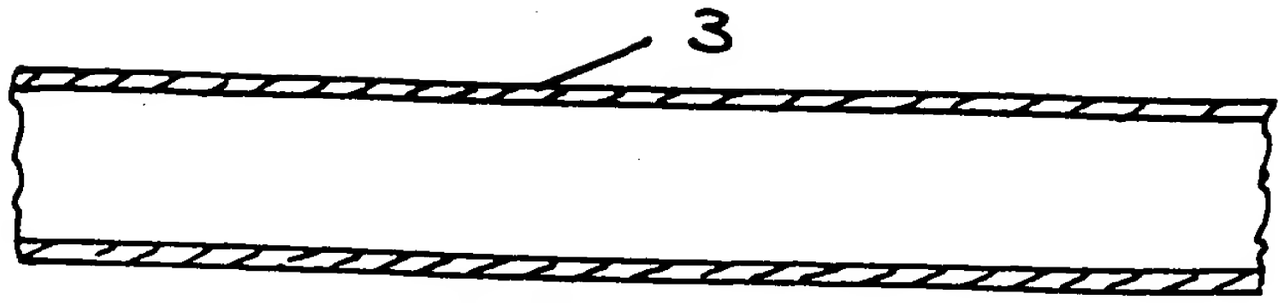

Fig. 3

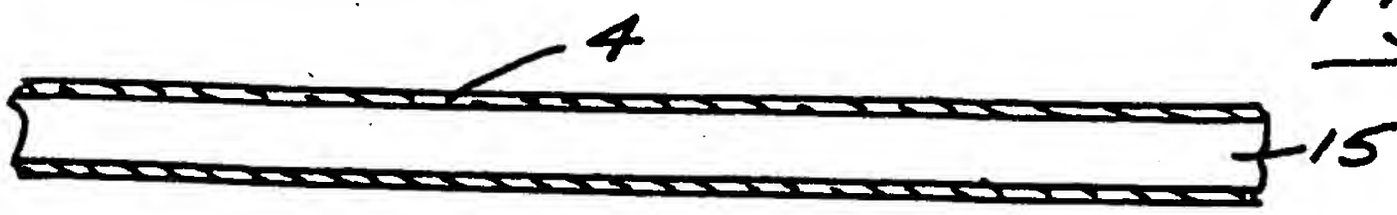

Fig. 4

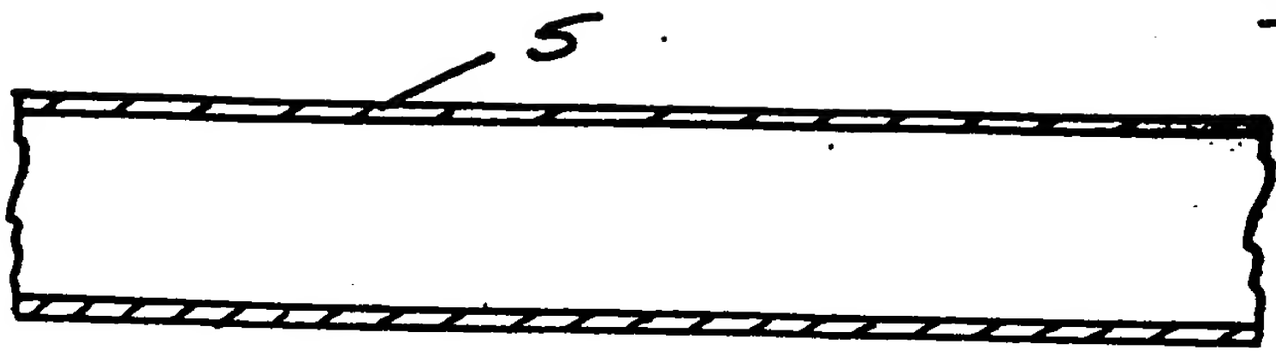

Fig. 5

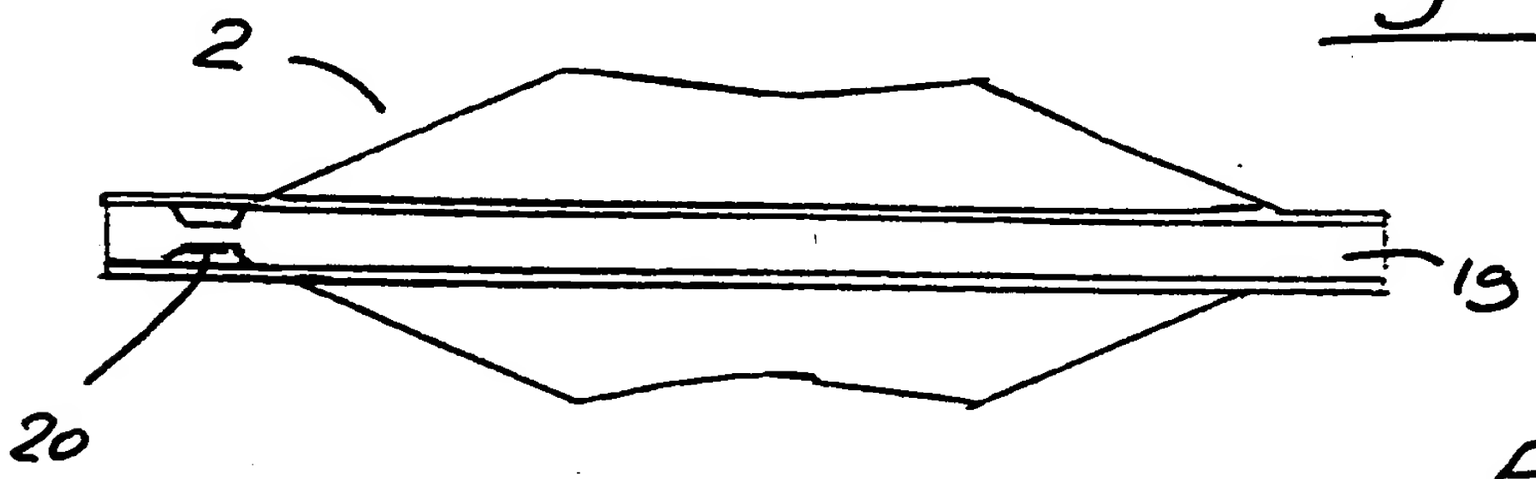

Fig. 6

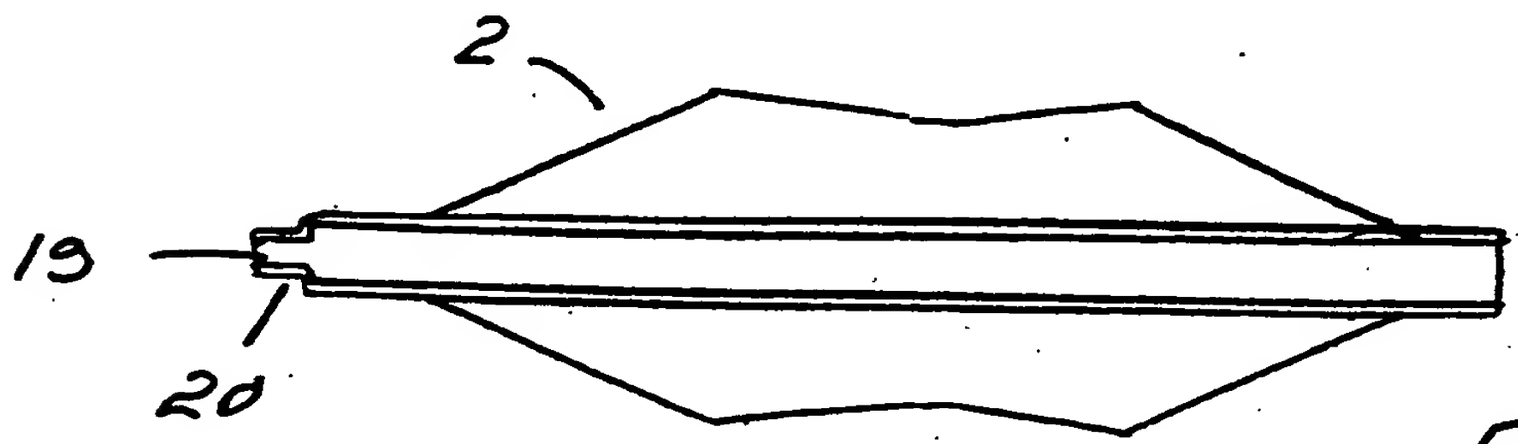

Fig. 7

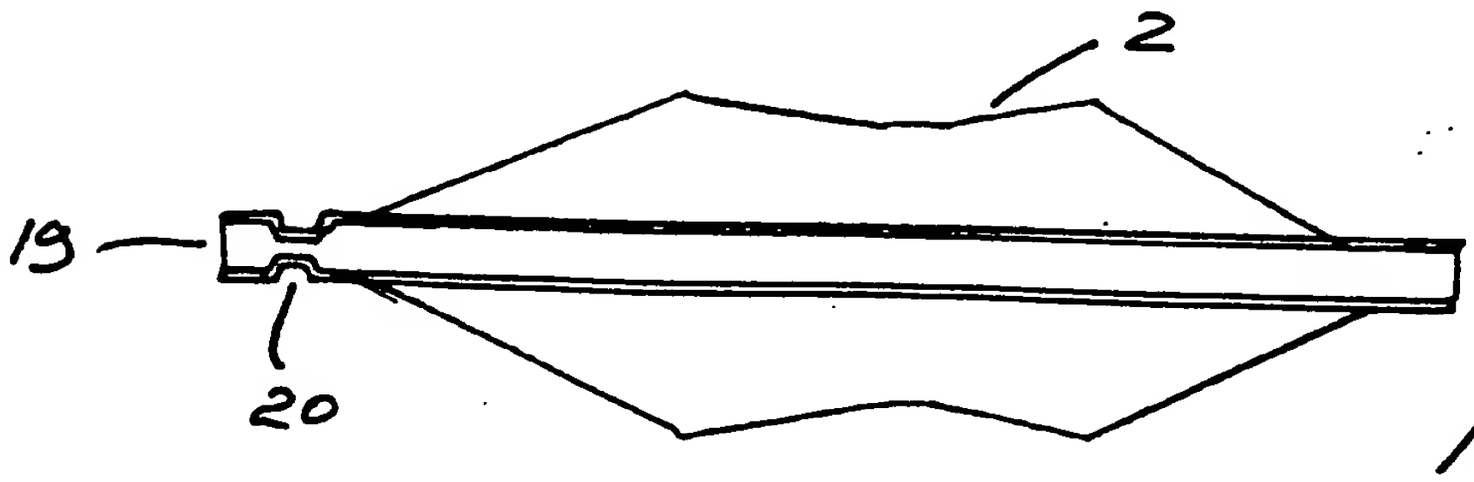

Fig. 8

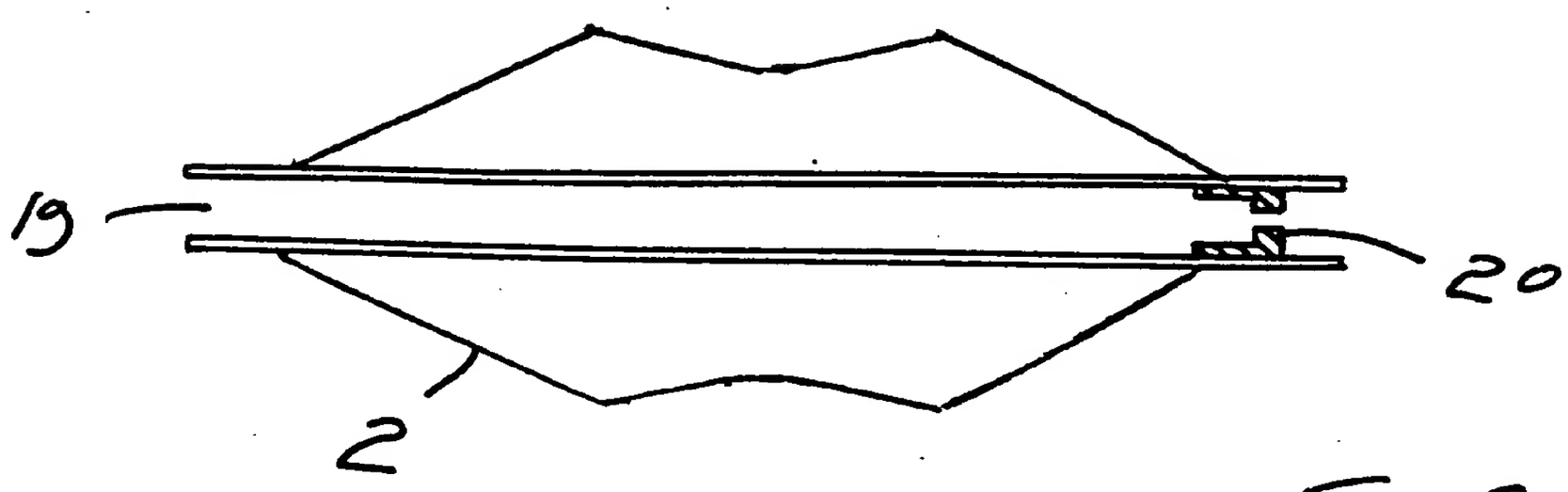

Fig. 9

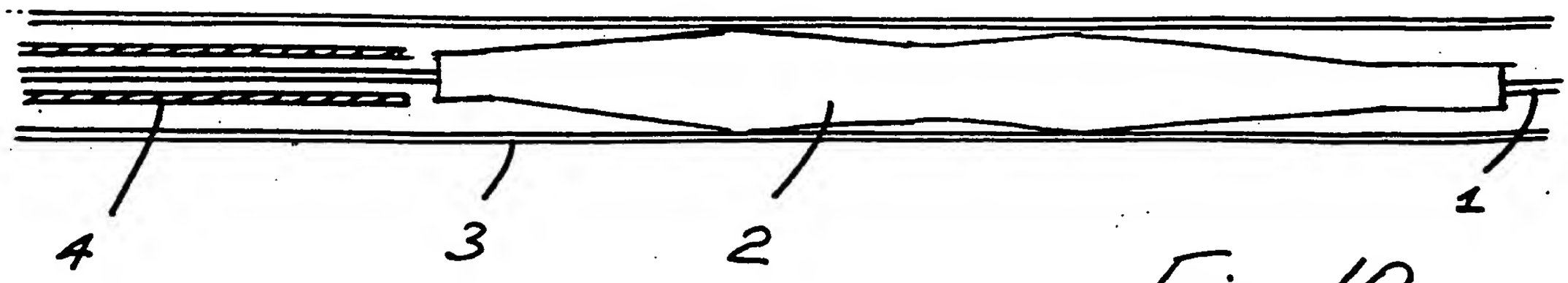

Fig. 10

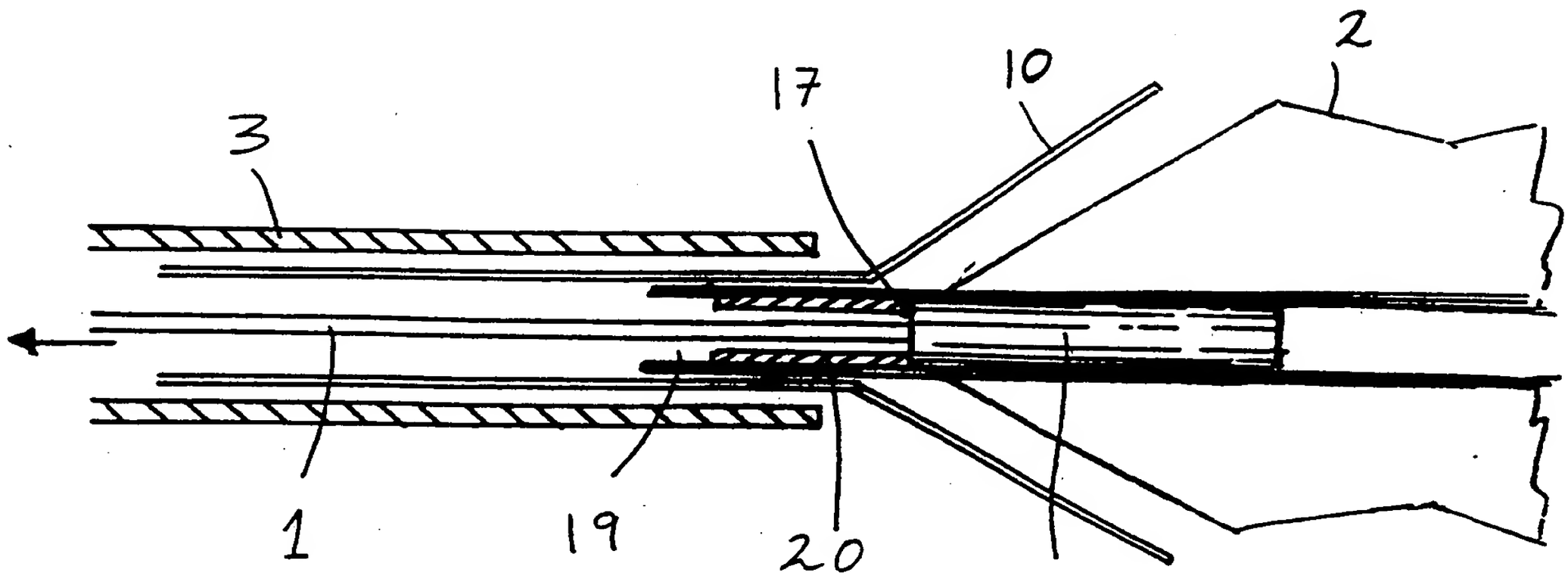

Fig. 11

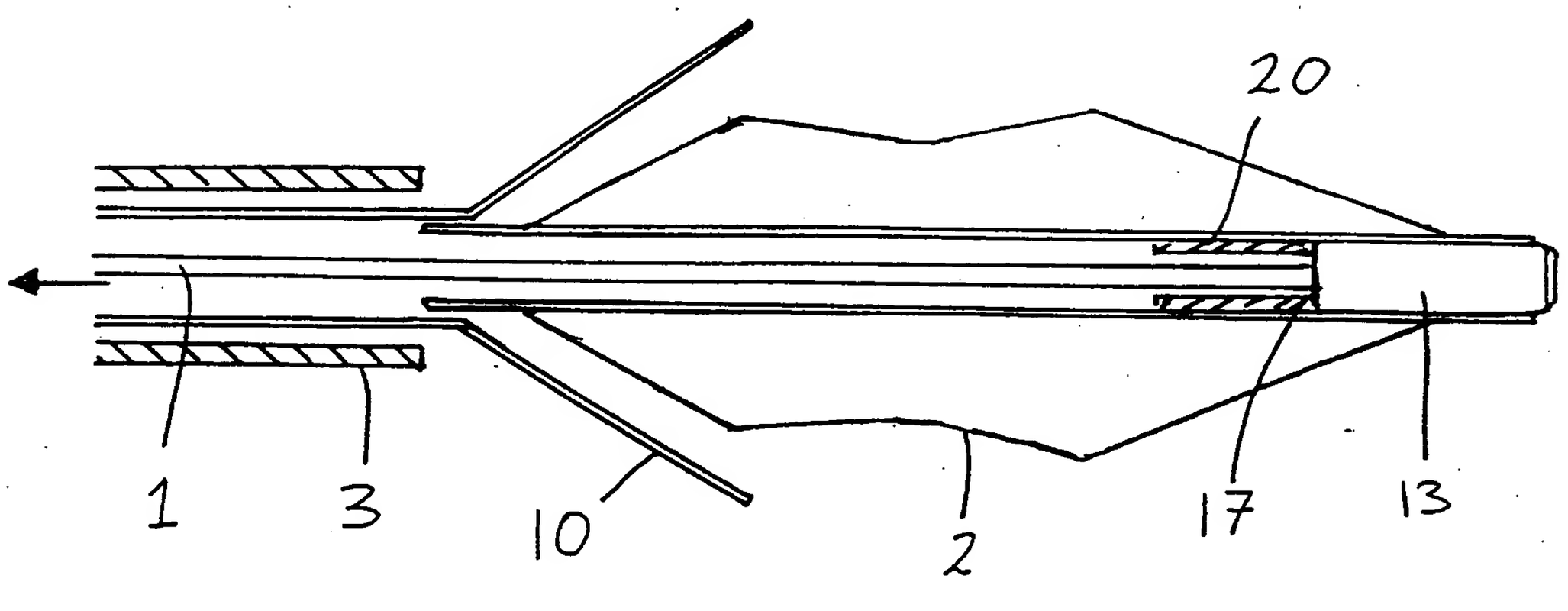

Fig. 12

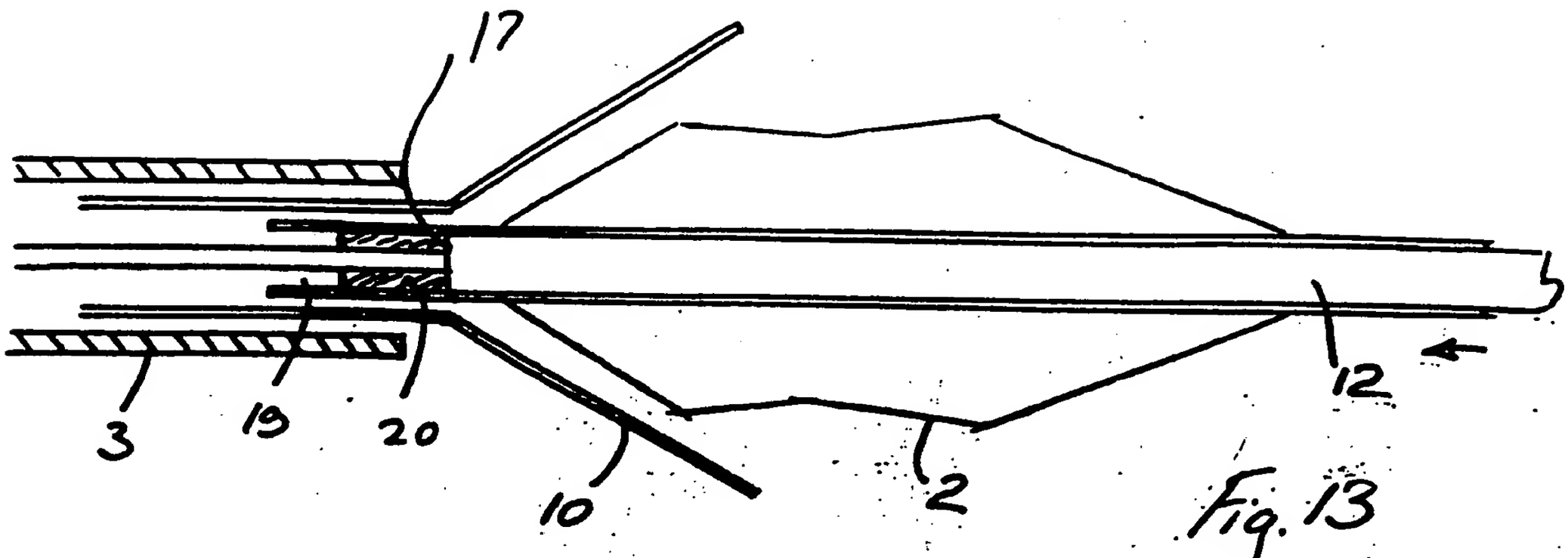

Fig. 13

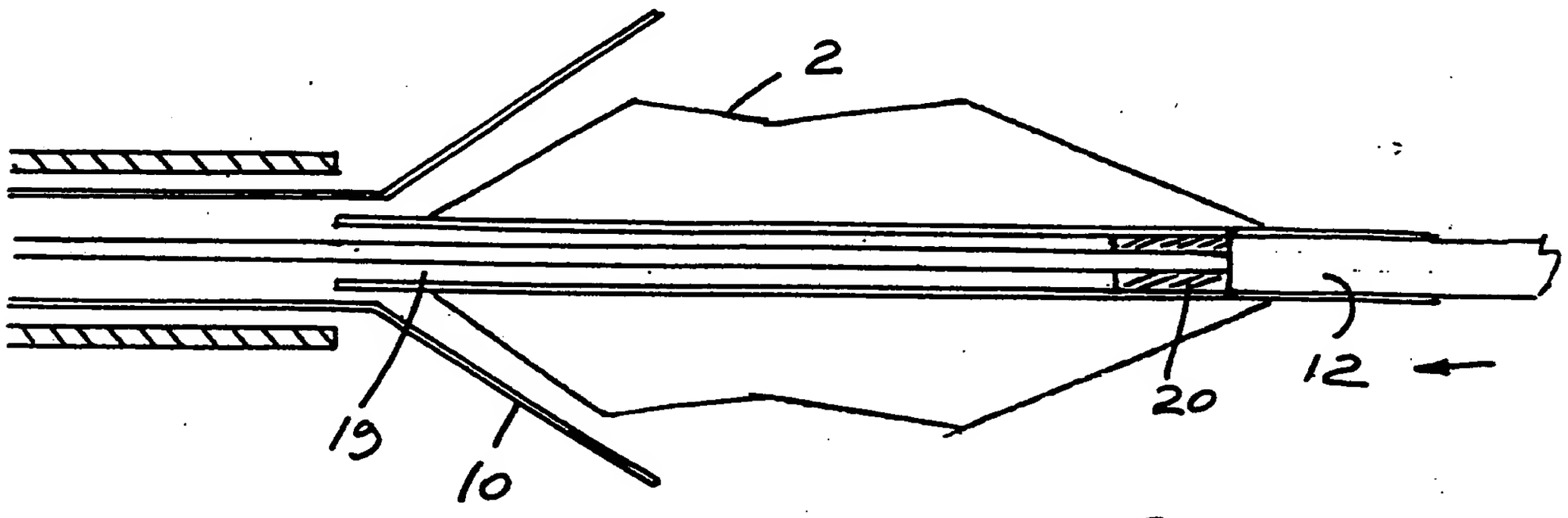

Fig. 14

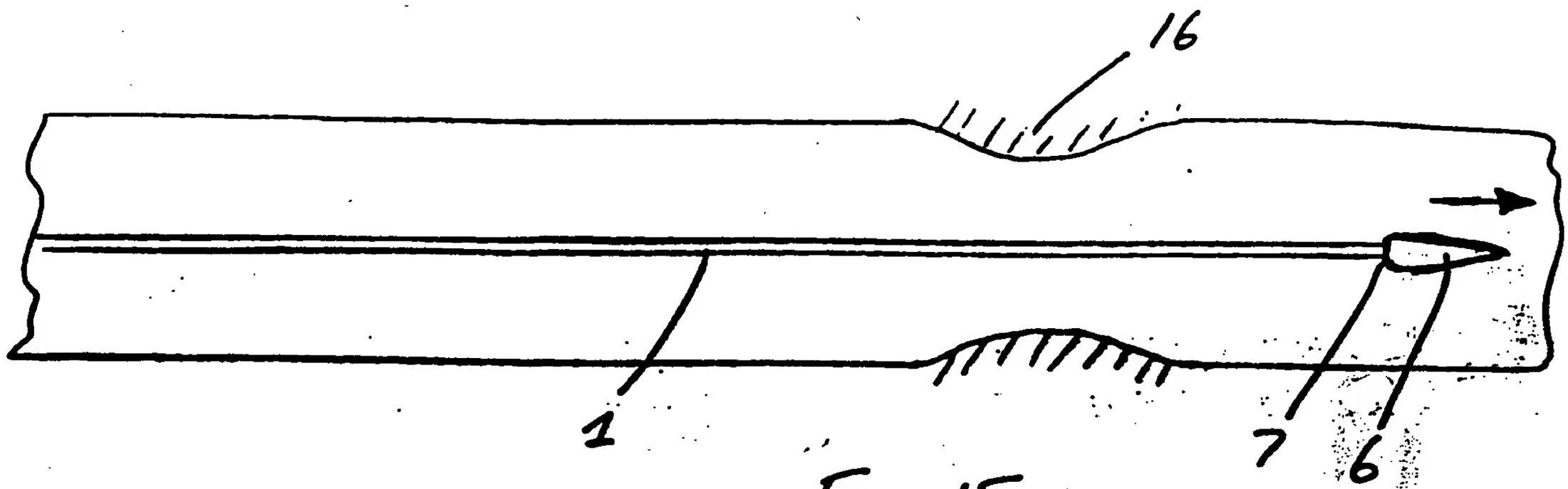

Fig. 15

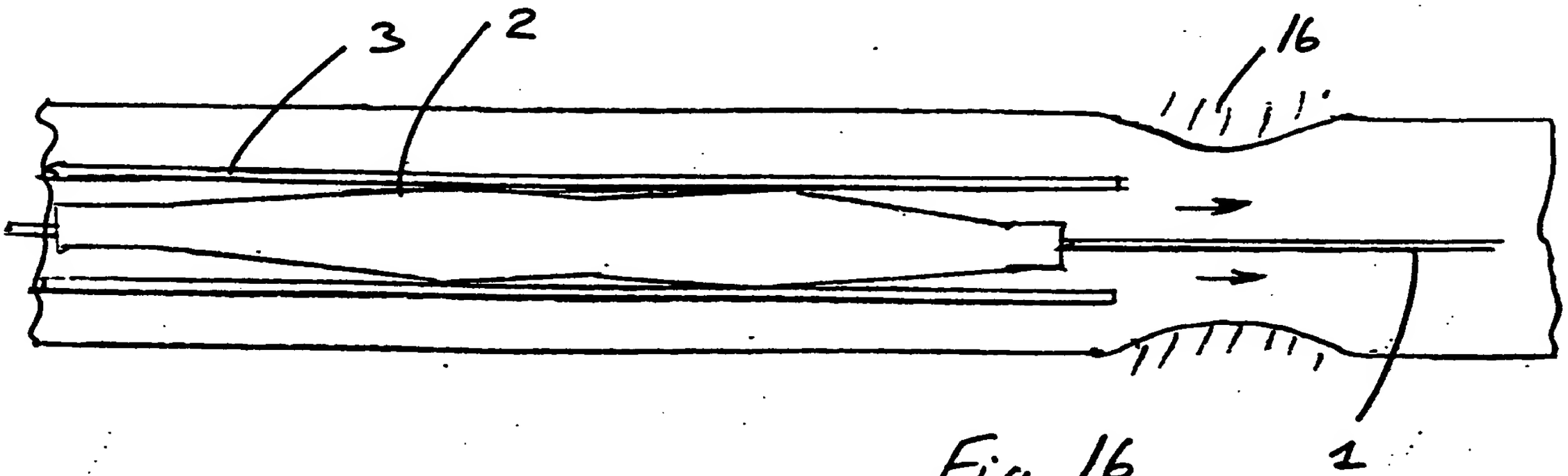

Fig. 16

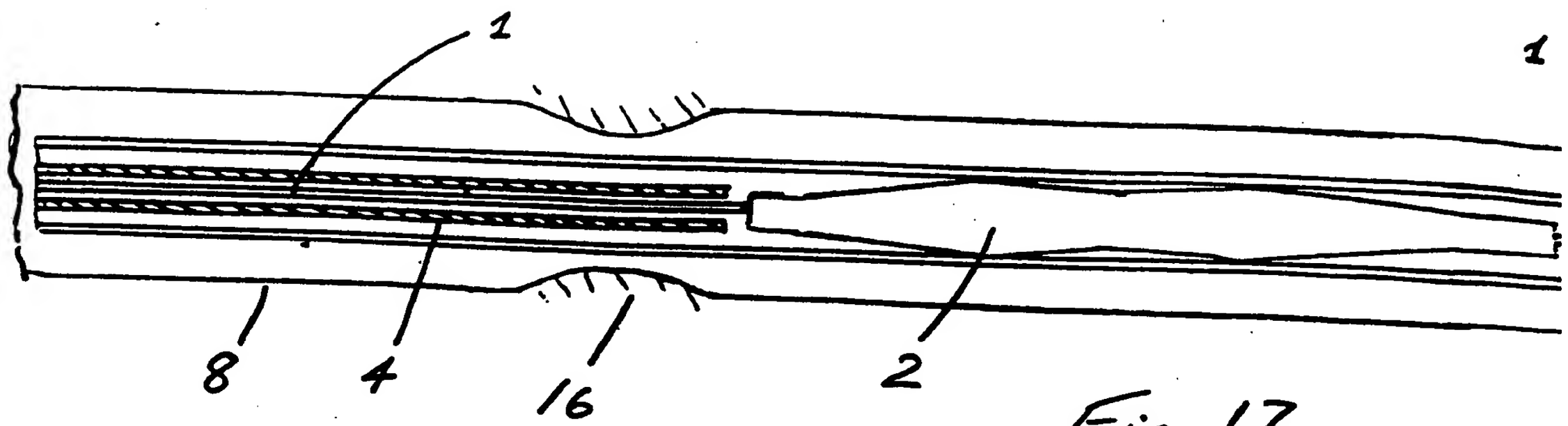

Fig. 17

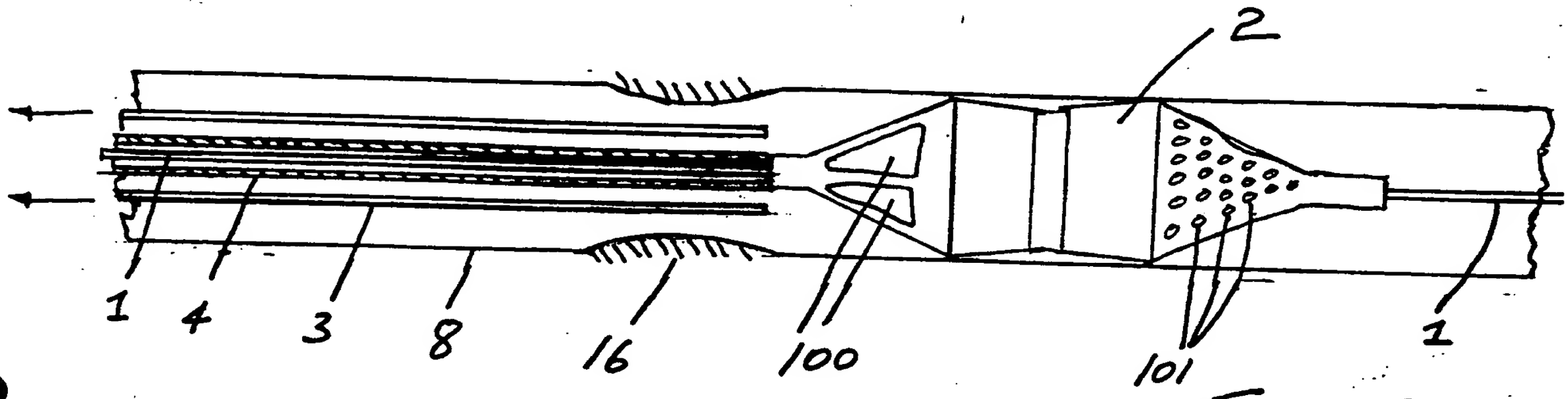

Fig. 18

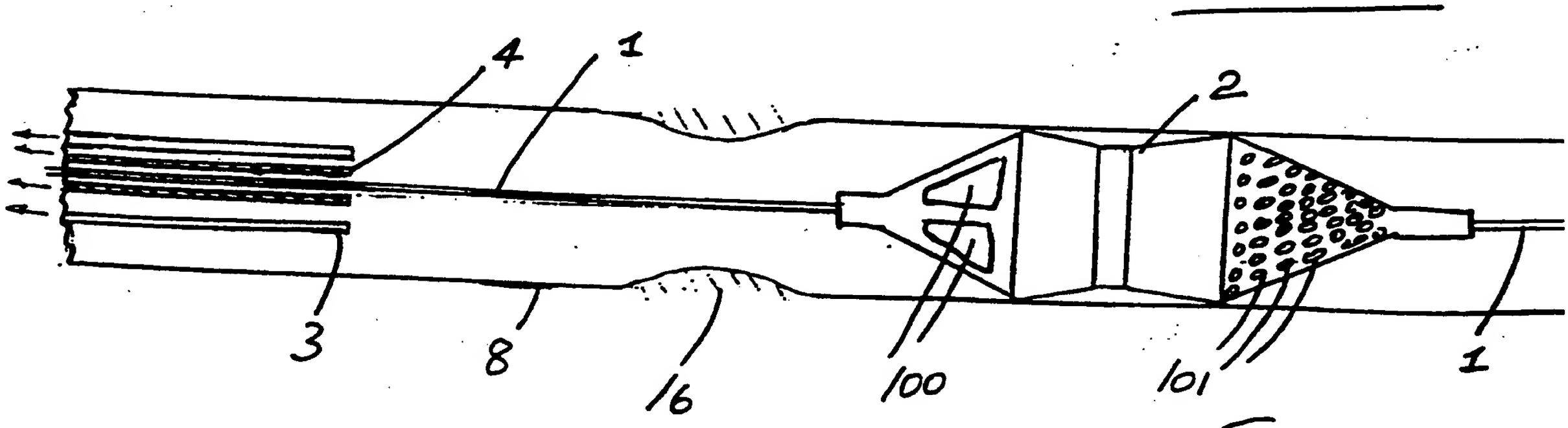

Fig. 19

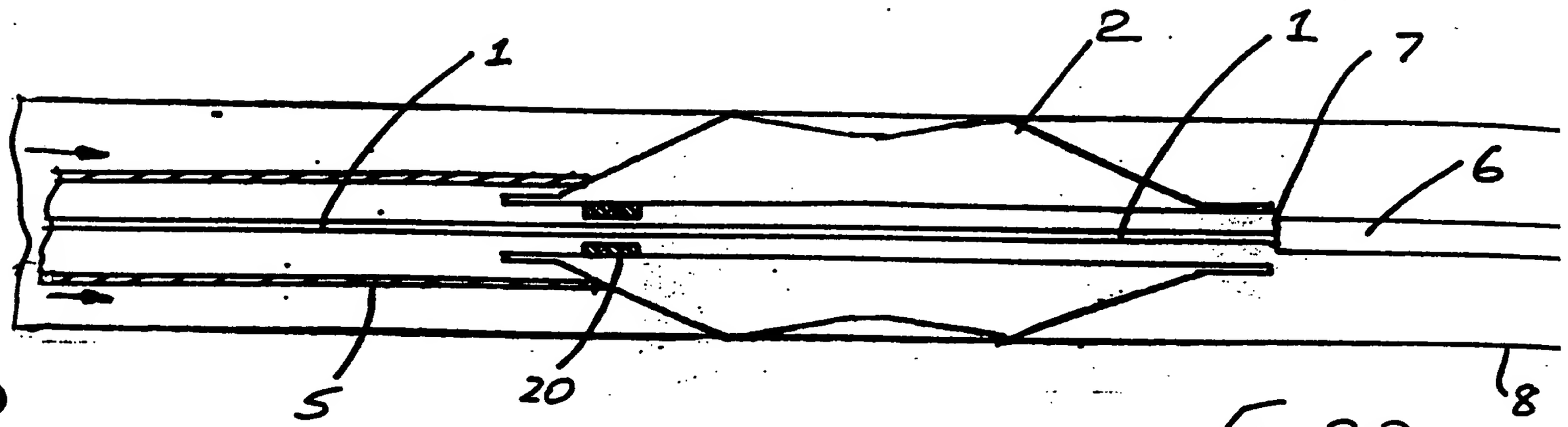

Fig. 20

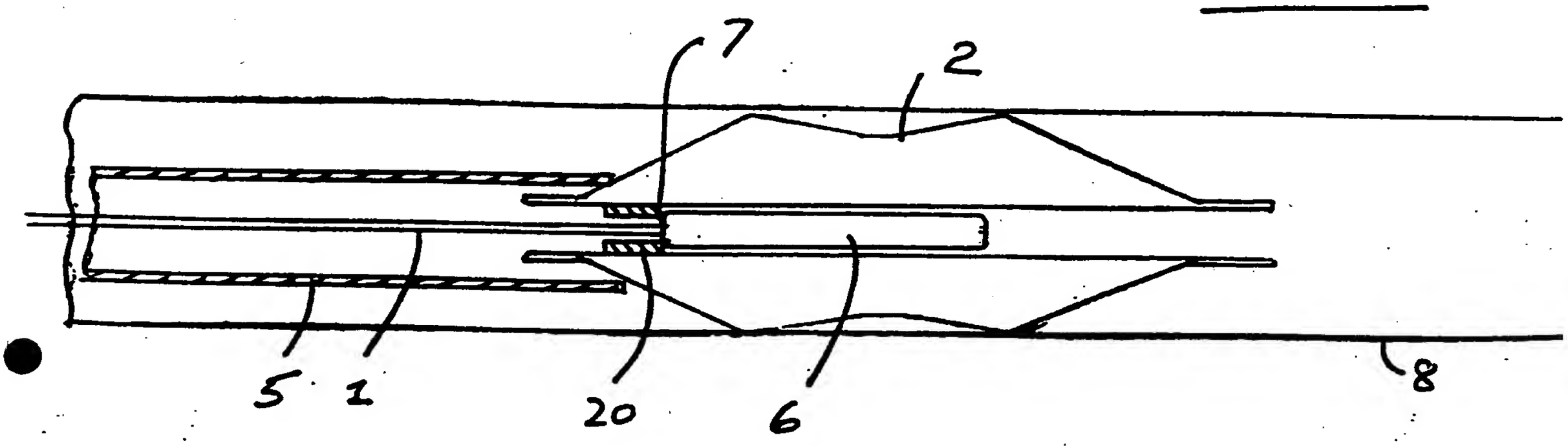

Fig. 21

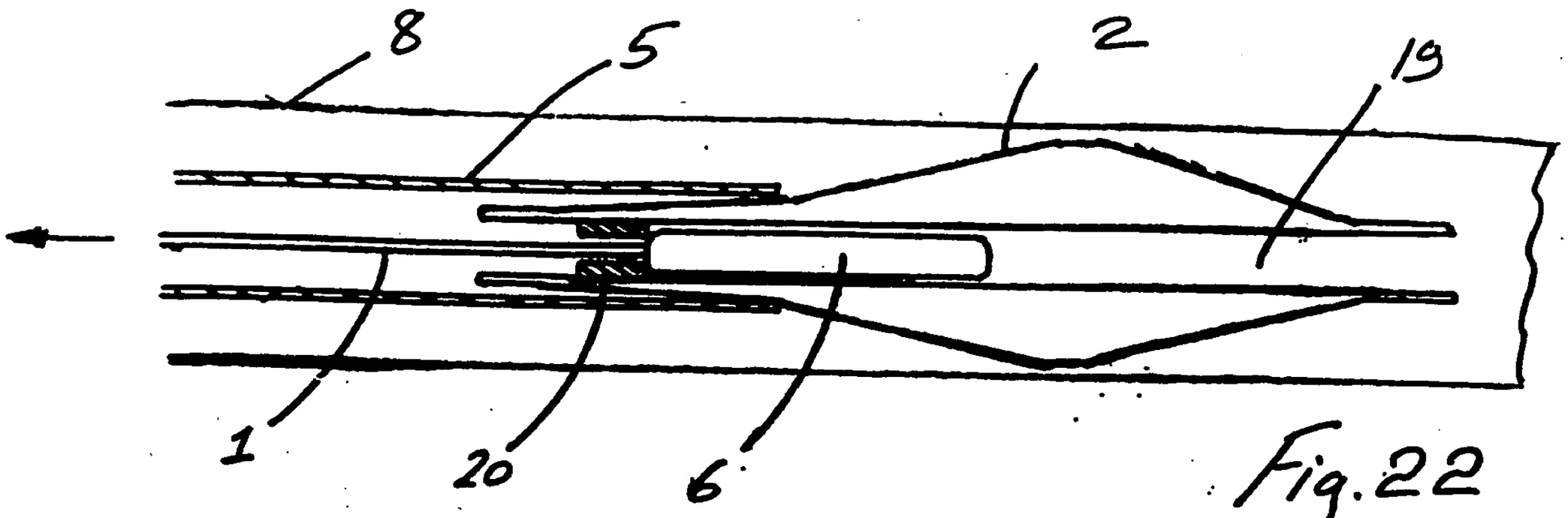

Fig. 22

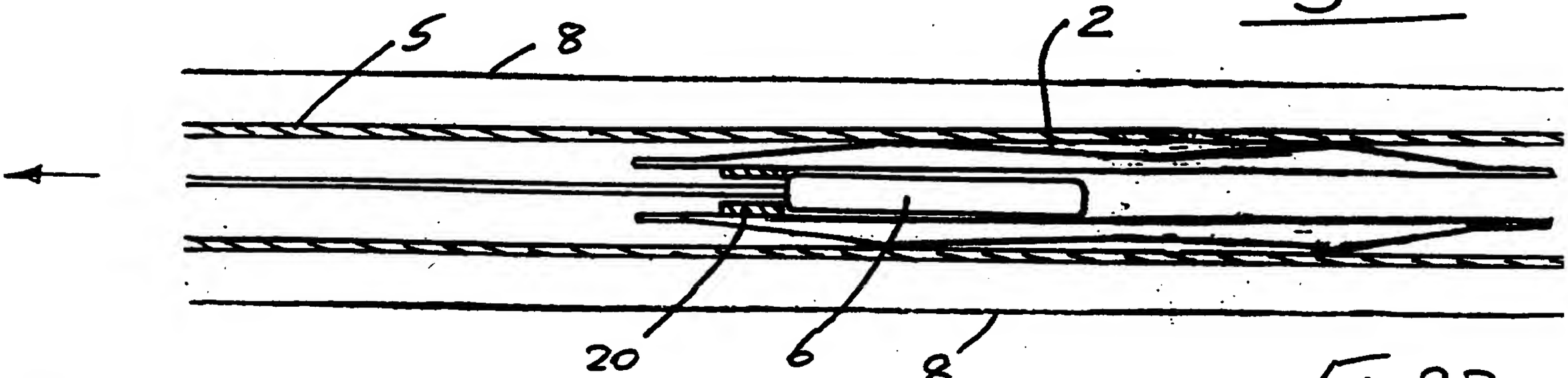

Fig. 23

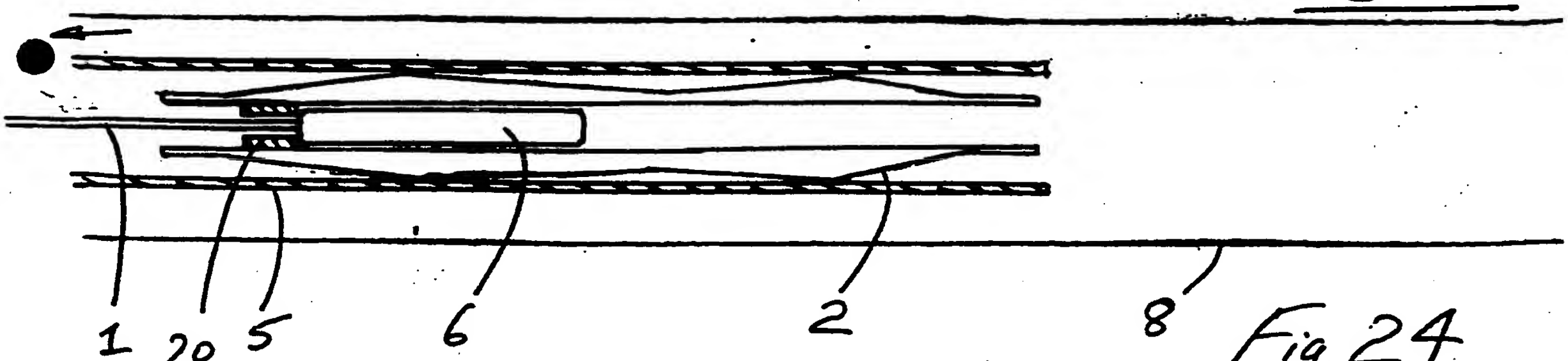

Fig. 24

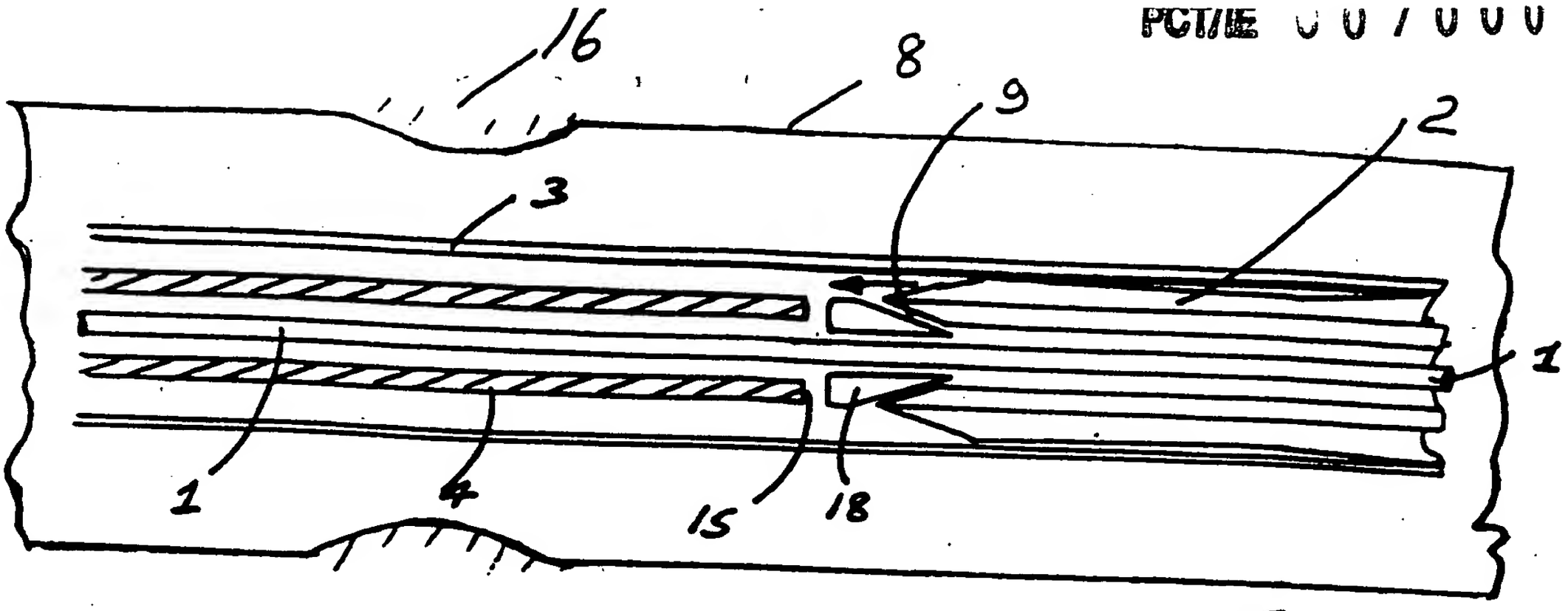

Fig. 25

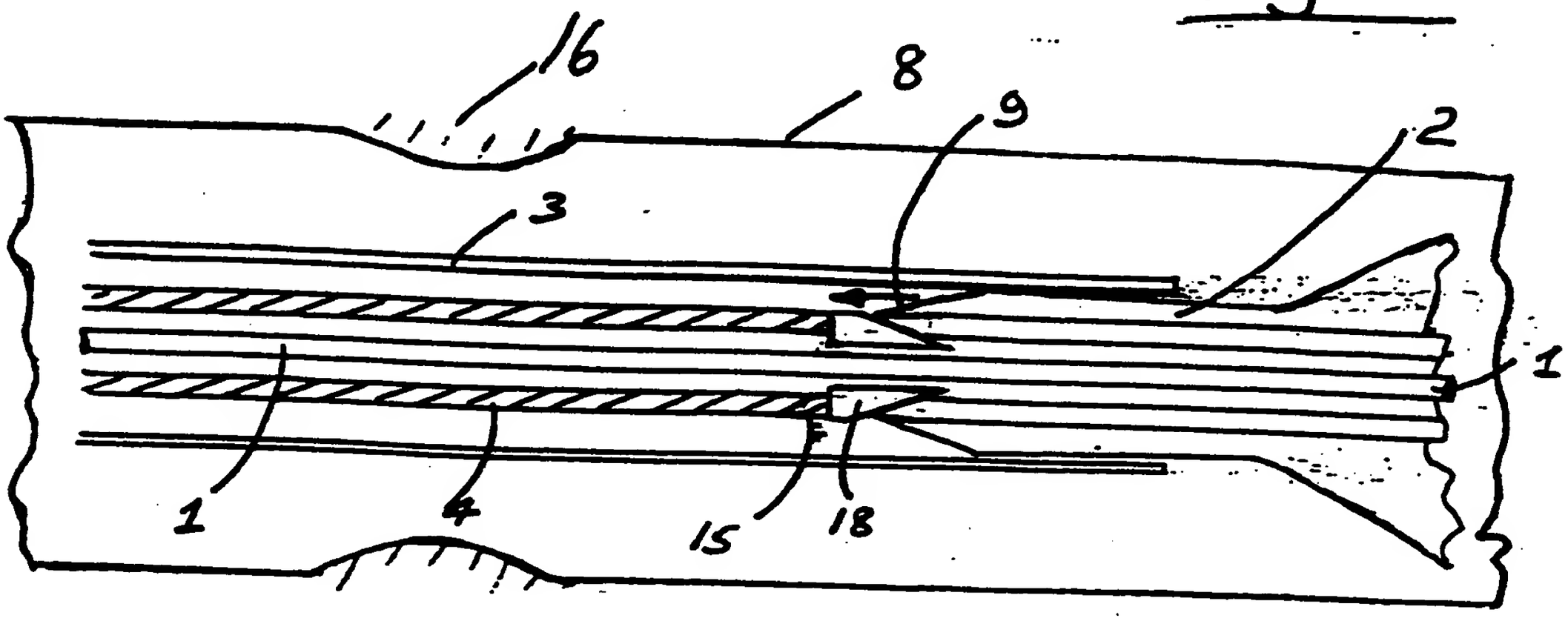

Fig. 26

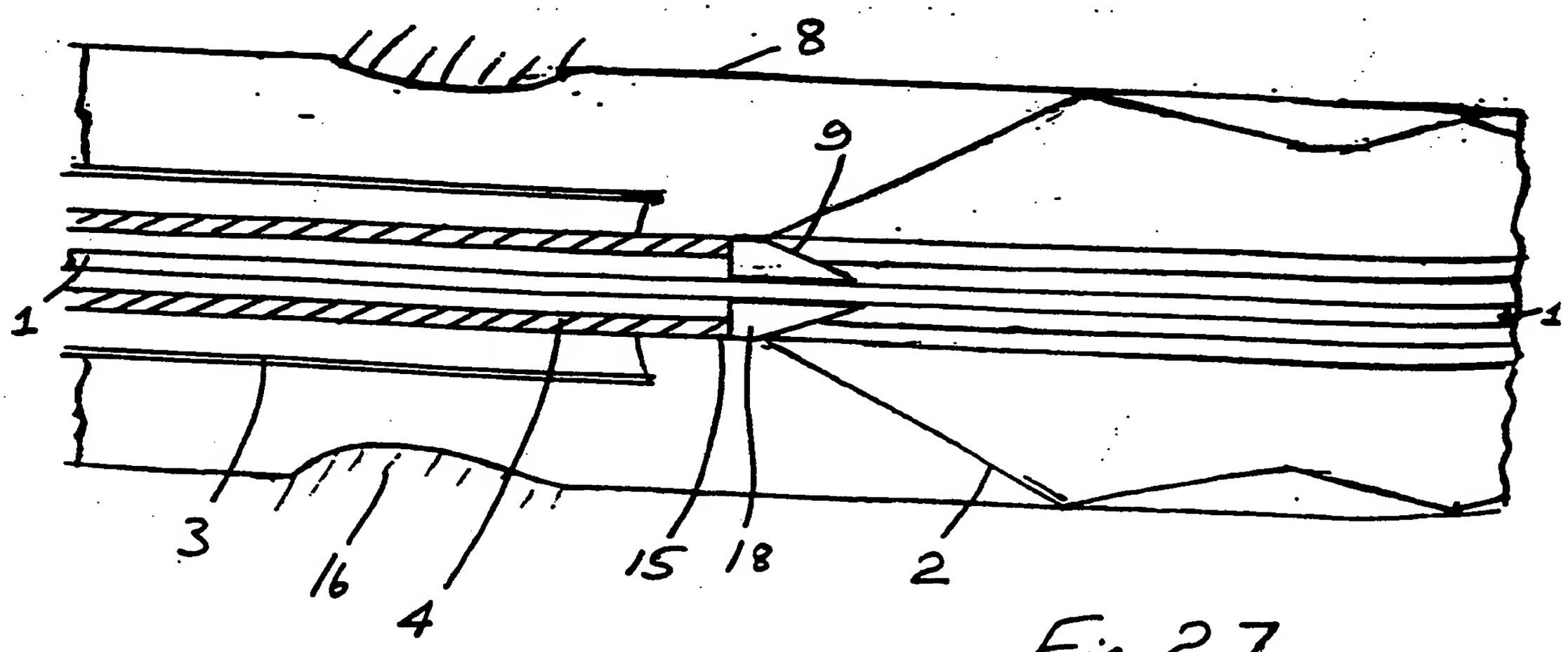

Fig. 27

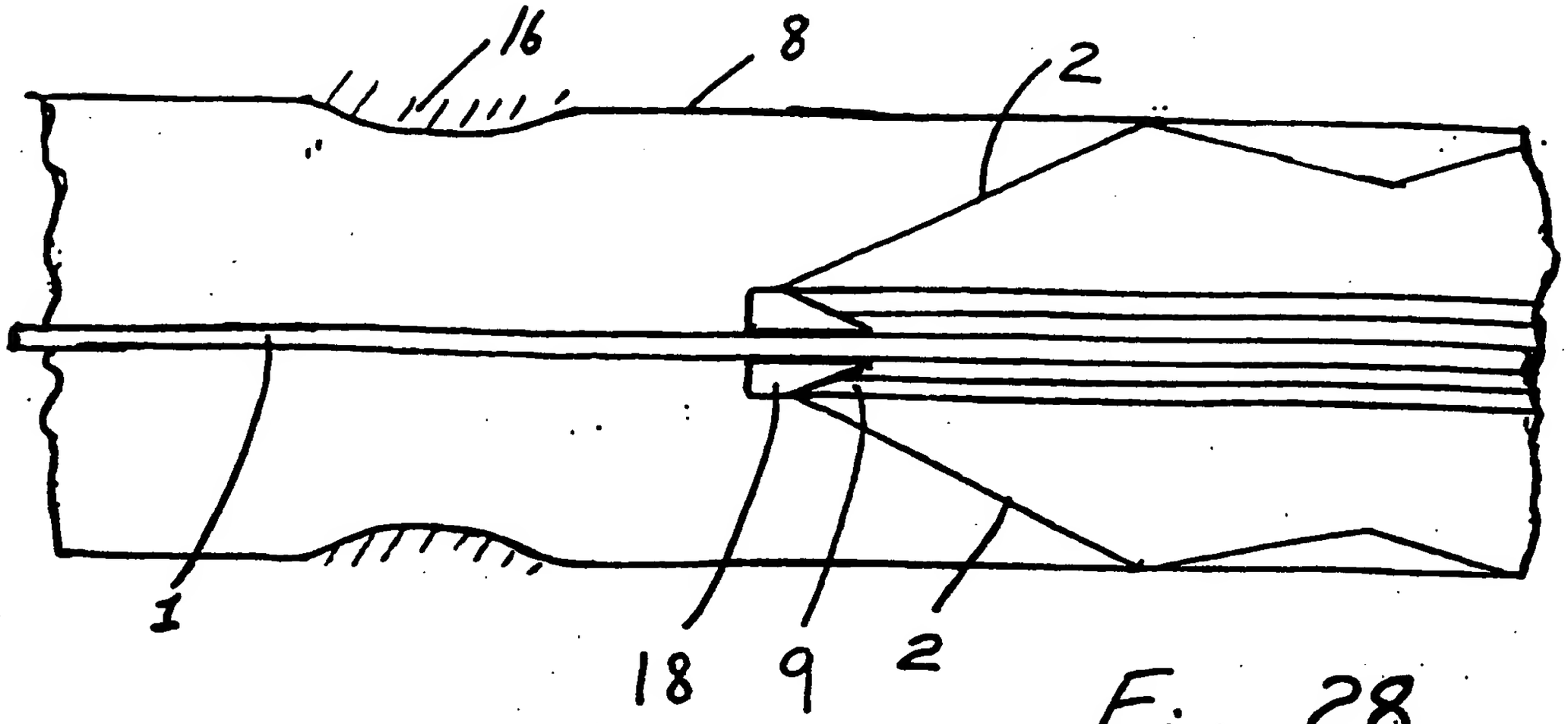

Fig. 28.

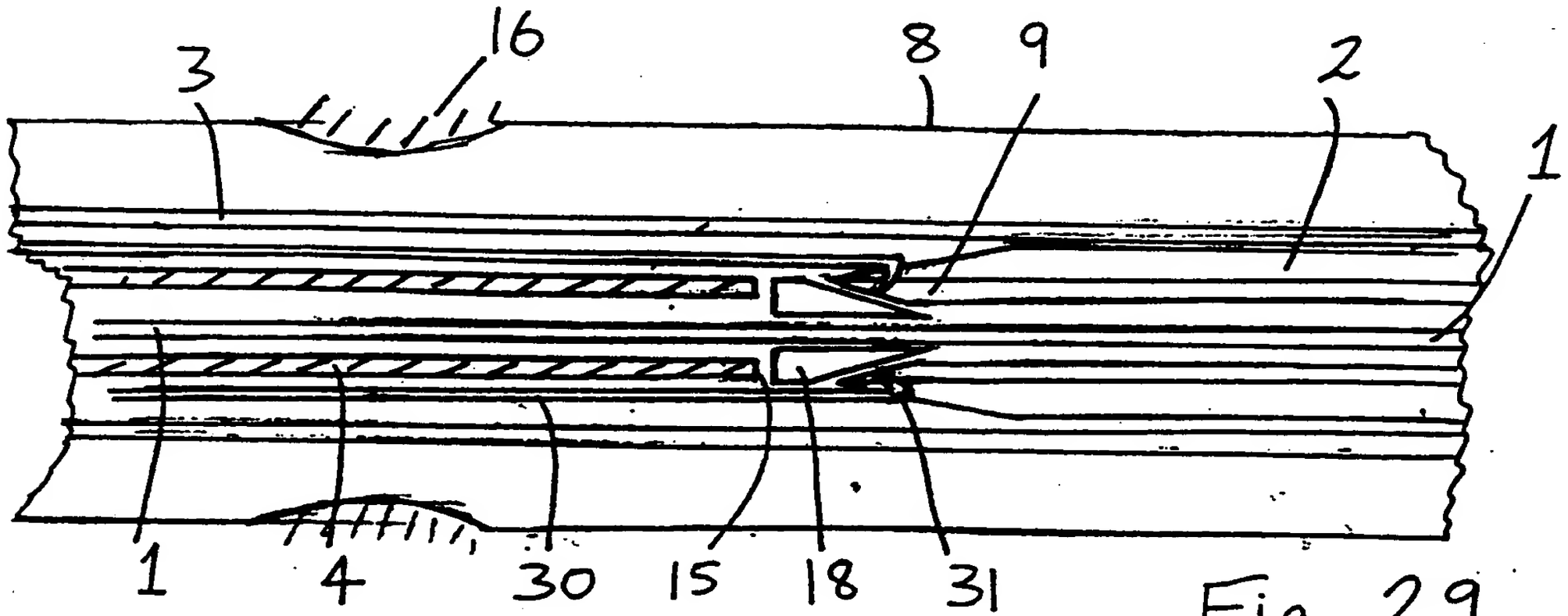

Fig. 29.

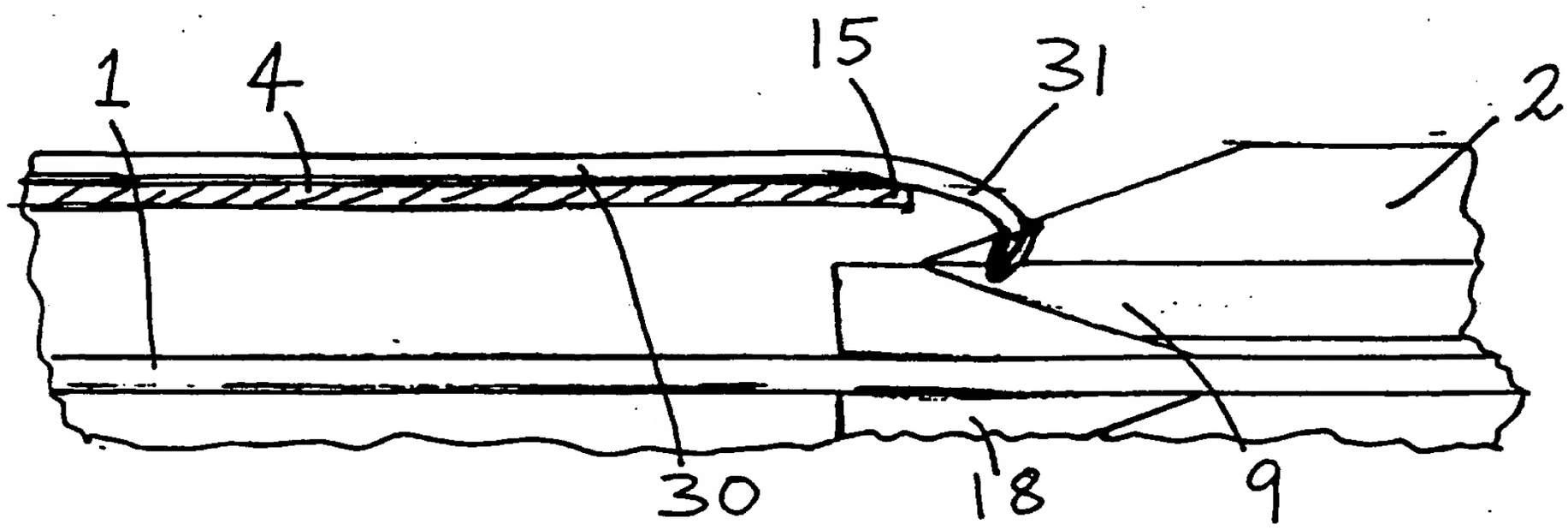

Fig. 30.

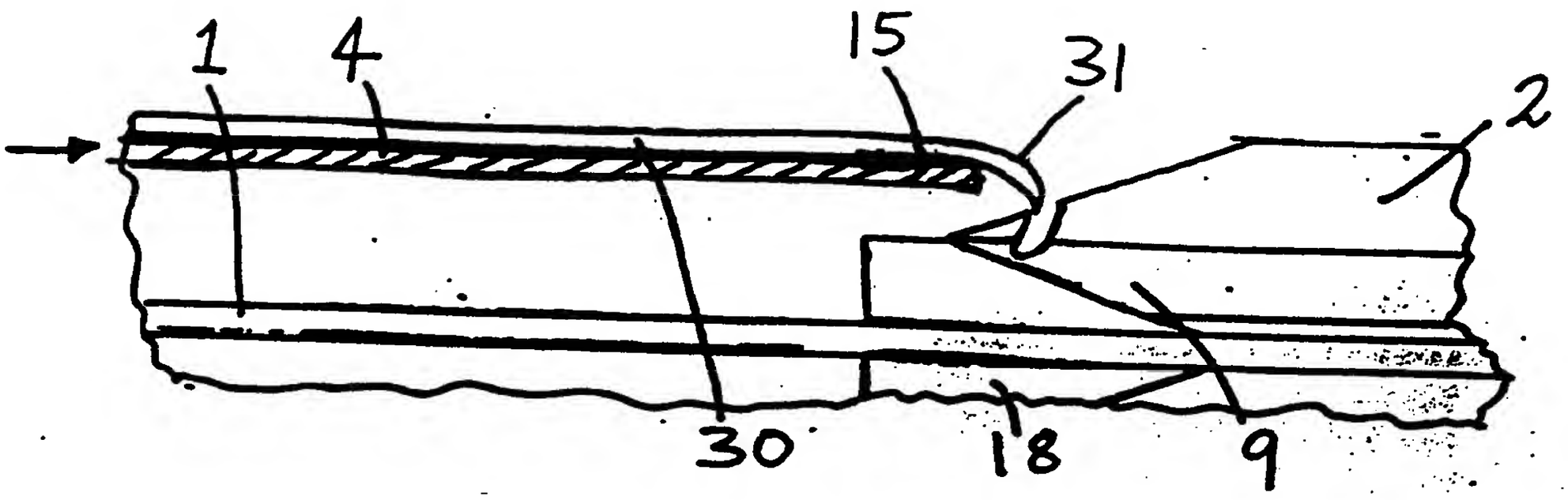

Fig. 31.

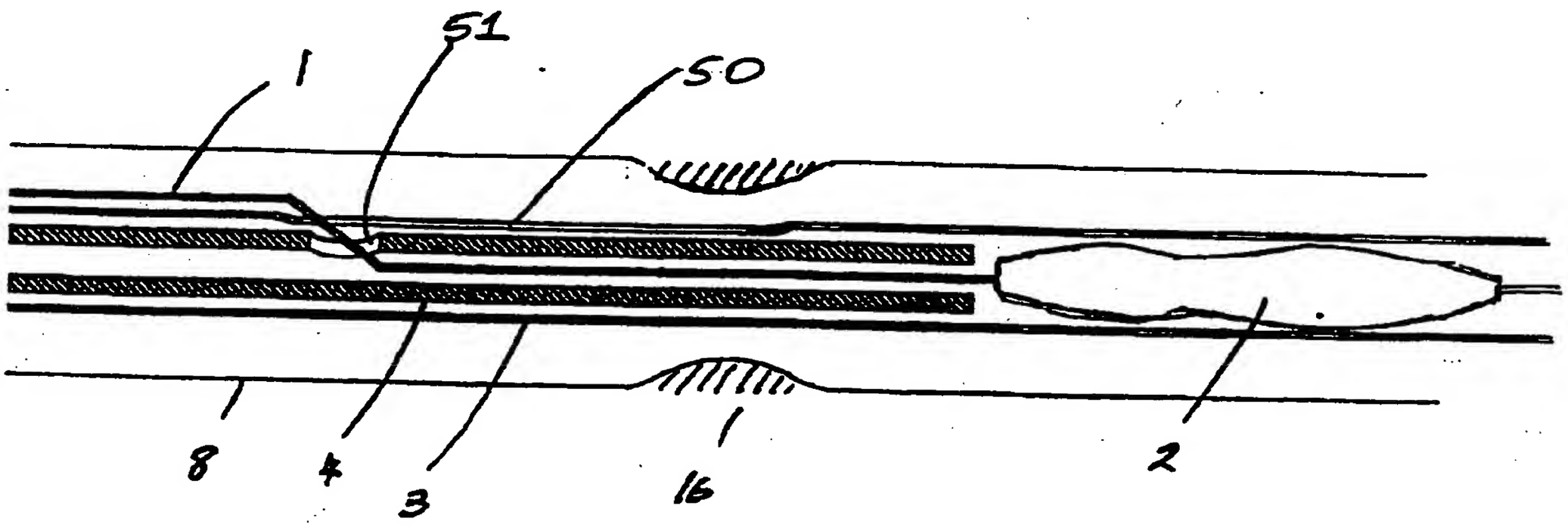

Fig. 32

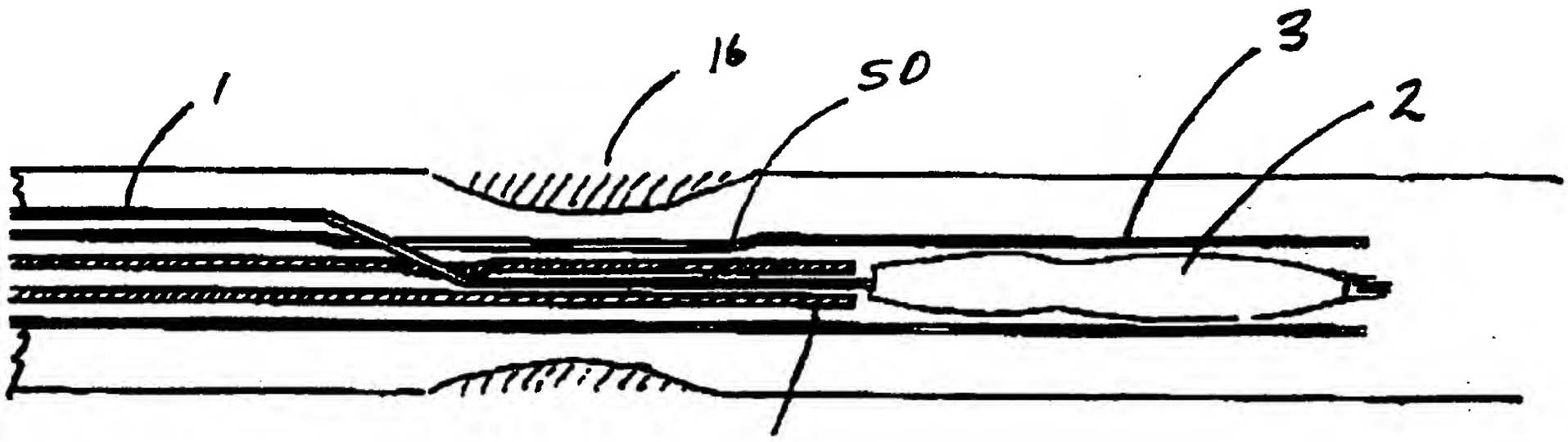

Fig. 33

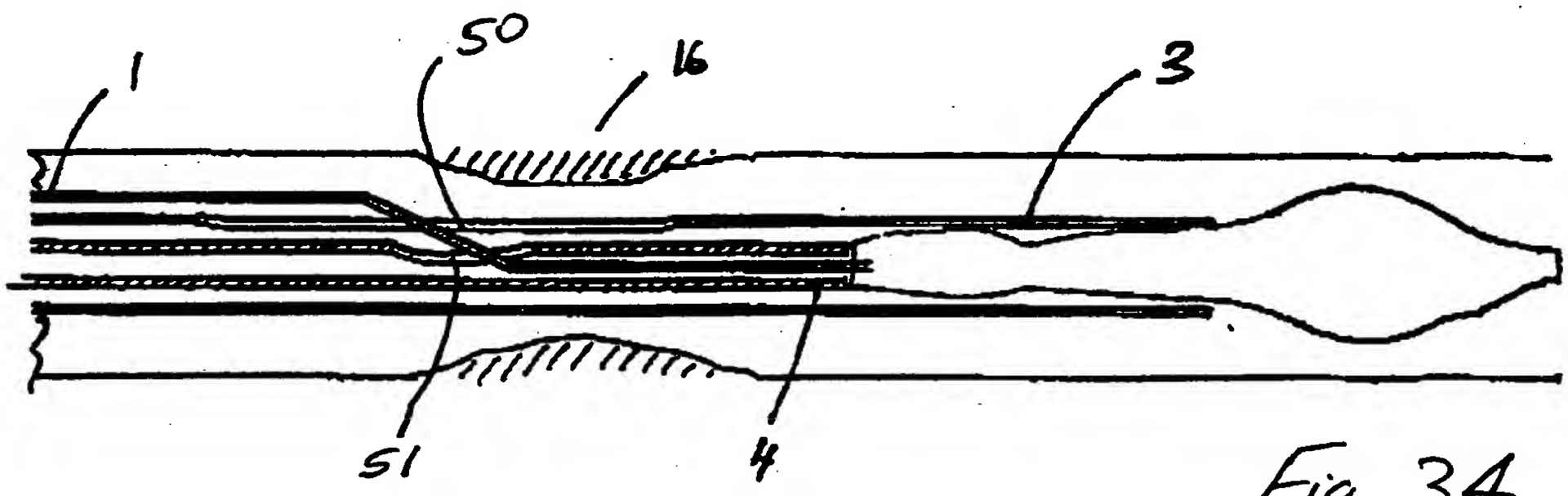

Fig. 34

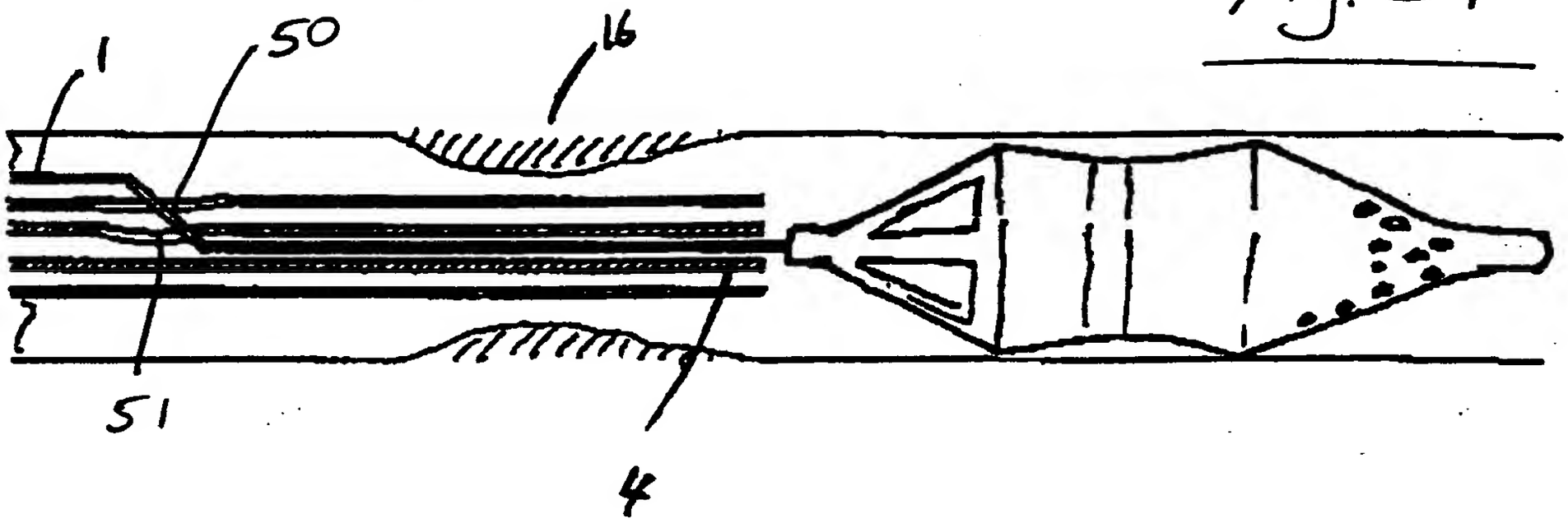

Fig. 35